

EPA Reg. Jacket 90354-2

PROCESSING REQUEST

Reg # 90354-2

Decision # 512219

Description: New Basic CSF

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 4/17/2017

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Tim Ciardo

Division: RD/IVB1

Phone: 703-347-8082

Date: 6/29/2017



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

90354-2

Date of Issuance:

6/29/17

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Yellow Jacket Killer!

Name and Address of Registrant (include ZIP Code):

David H. Dawe
President, D.H. Dawe & Associates, LLC (Agent)
2 Star Solutions Inc.
1954 East Bay Street
Hoschton, GA 30548

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Kable Bo Davis, Product Manager 03
Invertebrate & Vertebrate Branch I, Registration Division (7505P)

Date:

6/29/17

2. You are required to comply with the data requirements described in the DCIs identified below:

- a. Fipronil GDCI-129121-1305
 GDCI-129121-1512

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCIs listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: <http://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-pesticide-re-evaluation-division>

- 3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
- 4. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 90354-2.”
- 5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 04/17/2017

If you have any questions, please contact Tim Ciarlo by phone at 703-347-8082, or via email at Ciarlo.Timothy@epa.gov.

FRONT

Yellow Jacket Killer!™
Kills Yellow Jacket Scavengers

4 Bait Stations Included

KEEP OUT OF REACH OF CHILDREN
CAUTION (PRECAUCION)

See back panel and enclosed insert for additional First Aid.

Directions for use and Precautionary Statements on Top and Back Panel

Active Ingredient:

Fipronil*.....9.1%
Other Ingredients.....90.9%
Total.....100.00%

*(5-amino-1-(2,6-dichloro-4-(trifluoromethyl) phenyl)-4-(1,R,S)
(trifluoromethyl) sulfinyl)-1-H-pyrazole-3-carbonitrile

Net contents: 0.3ml (0.01 oz.)

EPA Reg. No. 90354-X

EPA Est. No. 90354-GA-001

ACCEPTED

06/29/2017

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 90354-2

TOP and BACK

FIRST AID
If Swallowed: Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.
If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a Poison Control Center or doctor for treatment advice. If Inhaled: Move person to fresh air. If person is not breathing call 911 or ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a Poison Control Center or doctor for treatment advice.
If in Eye(s): Hold eye open and rinse gently with water for 15 to 20 minutes. If wearing contacts, rinse eye for 5 minutes, remove contact and continue rinsing. Call a Poison Control Center or doctor immediately for treatment advice.
Note to Physician: There is no specific antidote. All treatment should be based on observed signs and symptoms of distress in the patient. Overexposure to materials other than this product may have occurred. In severe cases of overexposure by oral ingestion, lethargy, muscle tremors, and in extreme cases, possibly convulsions may occur.
Have the product container or label with you when calling a Poison Control Center or doctor, or going for medical treatment. You may also call SafetyCall at 866-897-6050 for emergency medical treatment information.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Caution: Harmful if swallowed, absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash any contaminated clothing.

NOTE: If you are allergic to yellow jacket stings, do not personally use this product. Have someone other than yourself handle and maintain the Yellow Jacket Killer!

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: Non-refillable Container: Do not reuse or refill this container. Triple rinse promptly after emptying; then offer for recycling, if available, or reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

ENVIRONMENTAL HAZARDS

The pesticide contained in the bottle is extremely toxic to fish and other aquatic invertebrates. Cover or collect spilled bait during loading. Do not discharge this product into lakes, streams, ponds, estuaries, oceans or other waters or sewage systems. Do not use within 25 feet of any body of water.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling. Read entire label before using this product. See enclosed instructions for Bait Station and complete Directions For Use.

LEFT SIDE

FINALLY! Now you have an easy-to-use product that kills yellow jacket scavengers.

Simply hang each Yellow Jacket Killer!™ bait station with treated bait inside and replace the bait daily for 5 consecutive days. **It's that easy!**

Bait Stations are made of transparent plastic that hang easily from a tree branch, shrub or other hanging location with the included twist ties.

Place Bait Stations near Yellow Jacket activity.

To kill yellow jackets, use multiple Bait Stations.

- Bait Stations should be placed no more than 60-75 feet apart.
- 1 bait station kit contains 4 bait stations.
- Use 4 bait stations for every 10,000 sq. ft. (100'x100') of area.

@2017 2 Star Solutions Inc. All rights reserved

RIGHT SIDE

Everything's Included!

The YELLOW JACKET KILLER!™ is the easiest way to solve your yellow jacket problem...because it's a product that kills Yellow Jacket scavengers.

CAUTION: If you are allergic to yellow jacket stings, do not personally use this product. Have someone other than yourself hang and maintain the Bait Stations.

U.S. Patent Pending

Made in the U.S.A.

EPA Reg. No. 90354-Pending EPA Est. No. 90354-GA-001

SOLD BY:

2 Star Solutions Inc.

970 Peachtree Ind. Blvd.

Suite 100

Suwanee, GA 30024

Questions or Comments? Call 1-888-448-1669

Batch No. _____



© 2017, 2 Star Solutions, Inc. All rights reserved.

YELLOW JACKET KILLER!™

Instruction Insert

YELLOW JACKET KILLER!™ allows the user to kill the yellow jackets without the dangers of applying an aerosol or powder pesticide to the nest. **YELLOW JACKET KILLER!™** is not a trapping device. This unique "Bait Station" is designed to attract yellow jackets and allow them to enter and feed on the pesticide-treated bait. The yellow jackets will leave the bait stations and die. Best of all, you do not need to know where the nest is located.

Active Ingredient:	Fipronil*.....	9.1%	* (5-amino-1-(2,6-dichloro-4-(trifluoromethyl) phenyl)-4-(1,R,S) (trifluoromethyl) sulfinyl)-1-H-pyrazole-3-carbonitrile
	Other Ingredients.....	90.9%	
	Total.....	100.0%	

STOP! READ ENTIRE DIRECTIONS BEFORE USE

Keep Out of Reach of Children

CAUTION

FIRST AID

If Swallowed: Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

If on Skin of Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for treatment advice.

If in Eyes: Hold eye open and rinse gently with water for 15 to 20 minutes. If wearing contacts, rinse eye for 5 minutes, remove contact and continue rinsing. Call a Poison Control Center or doctor immediately for treatment advice.

Note to Physician: There is no specific antidote. All treatment should be based on observed signs and symptoms of distress in the patient. Overexposure to materials other than this product may have occurred. In severe cases of overexposure by oral ingestion, lethargy, muscle tremors and, in extreme cases, possibly convulsions may occur.

Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment. You may also contact the Poison Help Line at 1-800-222-1222 for treatment advice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if swallowed, absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

PRECAUTION. Yellow jacket stings can be life threatening to persons who are allergic to the venom. People who develop hives, difficulty breathing or swallowing, wheezing or similar symptoms of allergic reaction should seek medical attention immediately if stung by a yellow jacket.

ENVIRONMENTAL HAZARDS

The insecticide contained in the dropper bottle is extremely toxic to fish and other aquatic invertebrates. Cover or collect spilled bait during loading. Do not discharge this product into lakes, streams, ponds, estuaries, oceans, or other waters or sewage systems. Do not contaminate water by disposal of waste. Do not use the product within 25 feet of any body of water.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product inconsistent with its labeling. For residential and commercial use. For non-food use only. **Do not hang bait station or replace bait if you are allergic to yellow jacket stings.**

INITIAL SET-UP: DAY 1

1. Open Bait Station and remove all contents.
2. Remove empty pesticide bottle and fill with clean water to fill line (88.7ml) marked on the bottle. Open pesticide blister package by bending back and forth at the scored line at the top of the bottle imprint. Carefully hold the blister packaging on the flat areas next to the top of the bottle imprint and tear off the top of the blister package. Squeeze entire contents into the water bottle. Insert dropper tip onto bottle top and replace bottle cap.
3. Remove four (4) bait trays, bait food packet and spoon. Add bait food to each of the bait trays (4 cubes each tray). Add one (1) level spoonful of water to each bait tray. Wait 1 to 2 minutes for bait to absorb the water. Shake insecticide bottle well (minimum 30 seconds). Add 2 drops of diluted insecticide to each cube of bait for a total of 8 drops per bait tray.

IMPORTANT: Yellow jackets will not take spoiled meat.

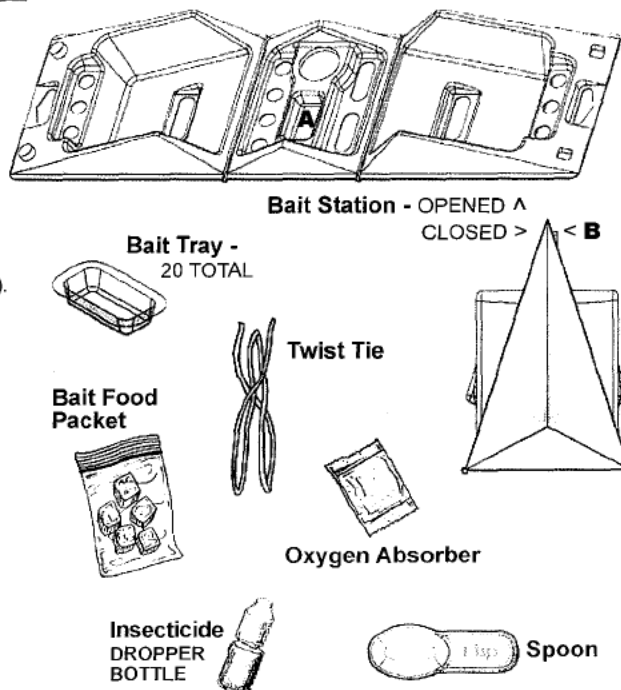
Replace bait trays and bait every morning for 5 consecutive days.

4. Insert loaded Bait Tray into Bait Tray receptacle - as shown in diagram A.
5. Close the Bait Station and press your fingers together on the button snap closures B.
6. Take the loaded Bait Stations and Twist Ties outdoors to hanging locations.
7. Attach the Twist Tie to the hanger opening at the top of the Bait Station.
Wrap the Twist Tie at least two (2) times around itself for secure attachment.
8. Hang the Bait Stations a minimum of 10 feet away from any known nest. Keep the Bait Stations away from your house or any outdoor living area.
9. Hang the Bait Stations in a SHADED AREAS for best results. NOTE: Using the Twist Tie, hang the Bait Station from a tree branch, shrub (or other hanging location) high enough from the ground that it cannot be reached by children, family pets or scavenging wildlife.
10. Wash hands thoroughly with soap and water immediately after handling Bait Station(s).

DAILY OPERATION: DAY 2 AND BEYOND

Perform the following steps every morning after Day 1:

1. Check Bait Station for yellow jackets. **If yellow jackets are present, do not attempt to change the bait.**
 2. If yellow jackets are not present, remove the Bait Station from the Twist Tie.
 3. Open Bait Station and remove used Bait Tray. Use a NEW Bait Tray and add 4 cubes of bait food to the tray. Add one (1) level spoonful of water to each bait tray. Wait 1 to 2 minutes for bait to absorb the water. Shake Insecticide bottle for a minimum of 30 seconds. Add 2 drops of diluted Insecticide to each bait cube for a total of eight (8) drops.
- IMPORTANT:** Yellow jackets will not eat spoiled meat.
Replace bait tray and bait every morning for 5 consecutive days.
4. Re-hang the Bait Station with the Twist Tie from the bait station hanger opening.
 5. Dispose of the used Bait Trays and bait into your trash receptacle.
 6. Wash hands thoroughly with soap and water immediately after re-hanging the Bait Stations and after handling the used Bait Trays.



BAIT STATION PLACEMENT

1. Hang Bait Stations in shaded areas, if possible, away from house and outdoor living areas.
2. Bait Stations should be placed no more than 60 to 75 feet apart. You will need 4 Bait Stations for every 10,000 sq.ft. of area.
3. Move Bait Stations to another location if yellow jackets are not finding and taking the bait.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Store unused product in its original container only, out of the reach of children and animals.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide is in violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional office for guidance.

CONTAINER HANDLING: Non-refillable Container: Do not reuse or refill this container. Triple rinse promptly after emptying; then offer for recycling, if available; or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved by the state and local authorities.

WARRANTY STATEMENT

2 STAR SOLUTIONS, Inc. warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for purposes stated on such label only when used in accordance with directions under normal use conditions. To the extent consistent with applicable law, the exclusive remedy of any buyer or user of this product for any and all losses, injuries, or damage resulting from or in any way arising from the use, handling, or application of this product, whether in contract, warranty, tort, negligence, strict liability, or otherwise, shall be damages not exceeding the purchase price paid for this product or, at 2 Star Solutions, Inc.'s option, the replacement of this product.

NET CONTENTS: One (1) blister packet of Insecticide 0.3ml (0.01 oz.)
One (1) blister packet of freeze-dried chicken (1.12 oz.)

EPA Reg. No. 90354-Pending EPA EST. No. 90354-GA-001 U.S. Patent Pending

SOLD BY: 2 Star Solutions, Inc.

970 Peachtree Industrial Blvd., Suite 100, Suwanee, GA 30024 1-888-448-1669



**Instructions
Instrucciones**

MADE IN THE U.S.A.



© 2017, 2 Star Solutions, Inc. All rights reserved.

Dropper Bottle Label

Yellow Jacket Killer!™

Active Ingredient:

Fipronil.....9.1%

Other Ingredients.....90.9%

Total.....100.00%

Keep out of reach of children

CAUTION

Read directions and precautionary statements
before using.

EPA Reg No. 90354-Pending

Net Contents: 88.75 ml



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Note to File

Date: June 27, 2017

Registration Number: 90354-2

Decision Number: 512219

PM/RM Name: Tim Ciarlo, RM

Kable Bo Davis, PM03

Background: This product (EPA Reg No. 90354-2) is the first fipronil bait designed for outdoor use against yellow jackets. There were a number of issues associated with this decision which require some explanation. They are described below.

1. There were ecological risk exceedances identified in EFED's Risk Assessment (DP 432832), specifically, acute and chronic risks to mammals. Label mitigation was implemented to ensure bait stations are applied such that they are inaccessible to mammals and other wildlife.
2. Although this product was assigned the R320 PRIA code (new physical form) it is essentially a 100% re-pack of an already registered product. The registrant is using the Formulator's Exemption to satisfy generic, acute tox, and product chemistry data requirements. Product-specific chemistry data was initially submitted with this application; however, it was determined to be unacceptable in a product chemistry review (DP 432824). The Formulator's Exemption approach was subsequently utilized to satisfy these data requirements.
3. Because efficacy data to support label claims against yellow jackets was not available to cite, the registrant has included these data on the data matrix dated 6/20/2017 (MRID 49797201). Efficacy data in this MRID does not support yellow jacket nest- or colony-kill claims. Based on additional clarifying information contained in an efficacy rebuttal (DP 439032), it was determined that "kills" claims against yellow jacket foragers or scavengers only are acceptable. The product label was adjusted accordingly.

Decision: EPA Reg No. 90354-2 was registered for outdoor use as a yellow jacket bait station product, with efficacy claims limited to yellow jacket foragers/scavengers only.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 90354-E	2. EPA Product Manager K. Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Yellow Jacket Nest Killer!	PM# 3	
5. Name and Address of Applicant (Include ZIP Code) 2 Star Solutions Inc. 1954 East Bay Street Hoschton, GA 30548 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated 1/18/2017	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Revised CSF and Data Matrix in response to Chemistry deficiencies.

Contact: dhdawe@dhdawe.com

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. _____ No. Per Container _____	If "Yes" Package wgt. _____ No. Per Container _____

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container Bulk	5. Location of Label Directions <input checked="" type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name David H. Dawe	Title President	Telephone No. (Include Area Code) 703-590-7570
-----------------------	--------------------	---------------------------------------------------

Certification

I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete.
I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title President, D.H. Dawe & Associates, LLC. (Agent)	6. Date Application Received (Stamped)
4. Typed Name David H. Dawe	5. Date 4/18/17	



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 90354-R	2. EPA Product Manager K. Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Yellow Jacket Nest Killer!	PM# 3	
5. Name and Address of Applicant (Include ZIP Code) 2 Star Solutions Inc. 1954 East Bay Street Hoschton, GA 30548 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Initial application for registration.

PRIA Category: R300

PRIA Fee: \$1,582

Contact: dhdawe@dhdawe.com

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. Per Container	If "Yes" Package wgt. No. Per Container

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container Bulk	5. Location of Label Directions <input checked="" type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name David H. Dawe	Title President	Telephone No. (Include Area Code) 703-590-7570
Certification I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title President, D.H. Dawe & Associates, LLC. (Agent)	
4. Typed Name David H. Dawe	5. Date 12/16/15	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 23, 2017

David H. Dawe
President, D.H. Dawe & Associates, LLC (Agent)
2 Star Solutions Inc.
1954 East Bay Street
Hoschton, GA 30548

Subject: R320 New Fipronil Product
EPA File Symbol: 90354-E
Product Name: Yellow Jacket Killer!
Application Dated: December 16, 2015
Negotiated PRIA Due Date: July 7, 2017
Decision Number: 512219

Dear Mr. Dawe:

The Agency has completed its review and assessment of your application pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a pre-decisional determination that your application cannot be approved unless revisions are made to the label. The necessary label changes are specified on the attached label. This version of the label was also emailed to you on June 23, 2017.

Since there is limited time before the PRIA Decision Due Date expires, it is important to discuss any objections you have to these changes immediately and whether you will need to submit additional data for review. If these discussions determine that submitting data will be necessary, the PRIA decision due date may need to be renegotiated to allow sufficient time to address and resolve such differences. If the PRIA Decision Due Date is not renegotiated, and the label issues are not resolved before the PRIA Decision Due Date, the Agency will send a follow-up letter that will represent the Agency's decision to close out the PRIA decision review time. The follow-up letter will provide the following three options for continuing the review of the application:

- (a) Applicant agrees to all of the terms associated with the draft accepted label as revised by the Agency and requests that it be issued as the accepted final Agency-stamped label; or

TRANSMITTAL DOCUMENT

Submitter

2 Star Solutions, Inc.
1954 East Bay Street
Hoshton, GA 30548

D.H. Dawe & Associates, LLC*
16841 Four Seasons Dr.
Dumfries, VA 22025

*D.H. Dawe & Associates, LLC. is the authorized agent for 2 Star Solutions, Inc.

Regulatory action in support of which this package is submitted

New Product Registration:
Yellow Jacket Nest Killer!

Transmittal Date


December 15, 2015

Contents

Vol. 1 Administrative Materials – Cover Letter; Application; Transmittal Document;
Small Business Fee Waiver Form; PRIA Fee Confirmation; Proposed Label;
Confidential Statement of Formula; Formulator's Exemption

49797201

Vol. 2 Efficacy studies on yellow jackets (*Vespula* sp.) with 2 Star Solutions, Inc. bait
stations in residential areas.

Company Official: David H. Dawe  12/16/15

Company Name: D.H. Dawe & Associates, LLC.

Company Contact: David H. Dawe (703) 590-7570

- (b) Applicant does not agree to one or more of the terms of the draft accepted label as revised by the Agency and requests additional time to resolve the difference(s); or
- (c) Applicant withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

If the applicant informs EPA that it has concerns as described under (b) above, the applicant will have up to 30 calendar days from the date of that follow-up letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA would intend to proceed with denial of the application.

If the applicant agrees to all of the terms of the accepted label as described in (a) above, or if the applicant and EPA resolve any differences as described in (b), the applicant must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to the applicant within 2 business days following the applicant's written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions, please contact Tim Ciarlo at 703-347-8082 or via email at Ciarlo.Timothy@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a large, hand-drawn oval.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure: Proposed label containing EPA edits sent via email June 23, 2017

Recommendation of Division Directors Negotiated Due Dates			
Decision #: 512219		Registration #: 90354-E	
		Petition #:	
<input type="checkbox"/> See page 2 for additional registration entries			
Chemical Name: Fipronil			
Fee Category: R320		PRIA Decision Time Frame: 12 months	
Submitted by: Timothy Ciarlo		Branch: OCSPP/OPP/RD	Date: 02/24/2017
Company: 2 Star Solutions, Inc.			
Original PRIA Due Date: 03/07/2017		Proposed New PRIA Due Date: 07/07/2017	
Previous Negotiated Due Dates:			
Is the "Fix" in-house? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> n/a		If not, date "Fix" expected: 02/24/2017	
Negotiated Due Date Reason:			
Additional Data Required	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Toxicology	<input type="checkbox"/> Acute Tox
	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Ecological	<input type="checkbox"/> Residue
Data Deficiencies	<input checked="" type="checkbox"/> Product Chemistry	<input type="checkbox"/> Acute Tox	<input checked="" type="checkbox"/> Efficacy
	<input type="checkbox"/> Environmental	<input type="checkbox"/> Ecological	<input checked="" type="checkbox"/> Labeling
Late Risk Assessment	<input type="checkbox"/> Human Health	<input type="checkbox"/> Ecological	
Interim Consideration	<input type="checkbox"/> Agency Initiated	<input type="checkbox"/> Registrant Initiated	
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental	<input type="checkbox"/> Risk Issues Human Health
<input type="checkbox"/> Impurities Review	<input checked="" type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice	<input checked="" type="checkbox"/> Other – Comment Field
Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input checked="" type="checkbox"/> Deficiencies (D)			
Product Chemistry: <input checked="" type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input checked="" type="checkbox"/> Labeling: <input checked="" type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input type="checkbox"/>			
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):			
Two separate 75-day letters were sent to the company. The first was sent 1/18/2017 and described product chemistry deficiencies. The second was sent 2/1/2017 and described efficacy deficiencies. The company requested a phone conference to discuss the 75-day letters, which occurred on 2/16/2017.			
"75 Day" Letter sent? <input checked="" type="checkbox"/> Yes, Date sent 01/18/2017 <input type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>			
Rationale for Proposed Due Date: Additional time needed to review chem data and efficacy rebuttal.			
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable			
Approve: <input checked="" type="checkbox"/>		Disapprove: <input type="checkbox"/>	
If disapproved, action to be taken:			
OD or DOD Signature: CN=Richard Keigwin/OU=DC/O=USEPA/C=US			Date: 02/24/2017

Decision #: 512219	Registration #: 90354-E	Petition #:

Issue(s) (describe in detail):

1. Efficacy - The efficacy data submitted to support claims against public health pests (yellow jackets in this case) were determined to be unacceptable for various reasons. The field study described in MRID 49797201 suffered from a lack of detail and a lack of replication. The applicant plans to submit a rebuttal 2/24/2017, which will be reviewed by PERC. The current PRIA due date of 3/7/2017 does not allow enough time for PERC to review this.
2. Product Chemistry - The applicant cited an incorrect MRID and then didn't respond in a timely manner with a corrected data matrix. The applicant plans to submit a revised data matrix with the correct data cited 2/24/2017. The current PRIA due date of 3/7/2017 does not allow the product chemistry team enough time to review this.
3. Labeling Issues - The label in its current form is lacking in many respects, including an application rate. Since we do not know the application rate, we cannot know if the rates tested in the efficacy study would be applicable. Multiple requests to address the proposed label were ignored by the company. We anticipate multiple rounds of label comments back and forth, which will take up more time than the current PRIA due date of 3/7/2017 allows.

Comment(s):

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv5.pdf

Form Number: PRIA

Document Identifier: PRIA-17053150913-TC

SUBMITTED on 02/24/2017 at 11:25:33 AM by CN=Timothy Ciarlo/OU=DC/O=USEPA/C=US

APPROVED on 02/24/2017 at 11:29:18 AM by CN=Cathryn Britton/OU=DC/O=USEPA/C=US

APPROVED on 02/24/2017 at 11:38:17 AM by CN=Meredith Laws/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 02/24/2017 at 03:52:05 PM by CN=Richard Keigwin/OU=DC/O=USEPA/C=US



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

February 1, 2017 #2

OPP Decision Number: D-512219

David H. Dawe
President, D.H. Dawe & Associates, LLC (Agent)
2 Star Solutions Inc.
1954 East Bay Street
Hoschton, GA 30548

Subject: Data Deficiency
Product Name: Yellow Jacket Nest Killer!
EPA File Symbol: 90354-E
Application Date: December 16, 2015
EPA Receipt Date: December 18, 2015

Dear Mr. Dawe:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending **April 17, 2017** to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are:

1. The efficacy data submitted in support of this proposed product are unacceptable. The attached Product Performance Data Evaluation Record (DER) (DP 432821) contains additional details.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

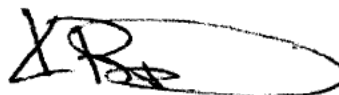
FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on March 7, 2017. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency not later than February 13, 2017 to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than February 13, 2017 that you are withdrawing your application. **As noted above, withdrawal concludes the Agency's review** of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee – Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by February 13, 2017, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by February 13, 2017 by contacting Tim Ciarlo or Kable Bo Davis by telephone at 703-347-8082 and 703-306-0415, respectively, or by e-mail at Ciarlo.Timothy@epa.gov or Davis.Kable@epa.gov during the hours of 8:00 am to 4:30 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure:

Product Performance Data Evaluation Record (DER) dated December 27, 2016 (DP 432821)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

January 18, 2017 #1

OPP Decision Number: D-512219

David H. Dawe
President, D.H. Dawe & Associates, LLC (Agent)
2 Star Solutions Inc.
1954 East Bay Street
Hoschton, GA 30548

Subject: Data Deficiency
Product Name: Yellow Jacket Nest Killer!
EPA File Symbol: 90354-E
Application Date: December 16, 2015
EPA Receipt Date: December 18, 2015

Dear Mr. Dawe:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending **April 3, 2017** to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are:

1. Group A and B Product Chemistry data, as well as a validated Enforcement Analytical Method, need to be submitted. The proposed product 90354-E was determined not to be similar to the cited product. Therefore, the cited product chemistry data included on the data matrix dated 4/6/2016 cannot support this proposed product. The attached Product Chemistry review (DP 432824) contains additional details.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on March 7, 2017. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency not later than February 13, 2017 to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than February 13, 2017 that you are withdrawing your application. **As noted above, withdrawal concludes the Agency's review** of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee – Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by February 13, 2017, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by February 13, 2017 by contacting Tim Ciarlo or Kable Bo Davis by telephone at 703-347-8082 and 703-306-0415, respectively, or by e-mail at Ciarlo.Timothy@epa.gov or Davis.Kable@epa.gov during the hours of 8:00 am to 4:30 pm EST with a response and for any questions

concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a large, loopy oval shape.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure:

Product Chemistry Review dated January 10, 2017 (DP 432824)

Ciarlo, Timothy

From: Davis, Kable
Sent: Monday, March 28, 2016 3:04 PM
To: Ciarlo, Timothy
Subject: FW: 90354-E
Attachments: Recode_90354-E.pdf

From: Yanchulis, Michael
Sent: Tuesday, March 01, 2016 10:11 AM
To: Davis, Kable <Davis.Kable@epa.gov>
Subject: RE: 90354-E

Hi Bo,

I have recoded the application as requested. A copy of the recoding letter is attached.

*Mick Yanchulis
Information Services Branch
Office of Pesticide Programs
U.S. Environmental Protection Agency*

From: Davis, Kable
Sent: Monday, February 29, 2016 4:23 PM
To: Yanchulis, Michael <Yanchulis.Michael@epa.gov>
Cc: Schaible, Stephen <Schaible.Stephen@epa.gov>
Subject: FW: 90354-E

As per
Hi Mick –

Would you please recode EPA File Symbol 90354-E (decision # 512219) from a R300 to a R320?

Thanks much for your help.
Bo

From: David Dawe [mailto:dhdawe@dhdawe.com]
Sent: Monday, February 29, 2016 4:19 PM
To: Davis, Kable <Davis.Kable@epa.gov>
Cc: 'Rick Matthews' [REDACTED]
Subject: 90354-E

Personal privacy information

Bo,

As per our discussion we would like to move forward with the registration of the Yellow Jacket Nest Killer. We understand we will need to pay additional fees after it is assigned a new PRIA code R320. As you indicated, we should expect a letter from Front End regarding the exact amount of the difference (\$2,910 per Steve). The PRIA due date will be set when the registration is recoded and, since it has to go outside of RD it is not likely the time can be compressed.

You will pass it on to a reviewer and we will get a prompt to forward the data matrix.

Dave

David H. Dawe, Ph.D.

D.H.Dawe & Associates, LLC.

16841 Four Season Dr.

Dumfries, VA 22025

Phone: (703) 590-7570

Cell: (559) 960-2245

email: dhdawe@dhdawe.com

Web Site: www.dhdawe.com



United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address 2 Star Solutions, Inc. 1954 East Bay Street Hoshton, GA 30548	EPA File Symbol/Registration Number
	90354-X
	Product Name
	Yellow Jacket Nest Killer!
Date of Confidential Statement of Formula (EPA Form 8570-4)	
4/17/2017	

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredients(s):

Fipronil

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

- ☒ (A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- ☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
<i>fipronil</i>	[REDACTED]	[REDACTED]
Signature	Name and Title David H. Dawe, Agent	Date 4/21/17



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.

Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number
2 Star Solutions Inc., 1954 E. Bay St., Hoschton, GA., 30548
770-217-1230

EPA Registration Number/File Symbol

90354-E

Active Ingredient(s) and/or representative test compound(s)
Fipronil

Date 4/6/2016

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
Outdoor, non-food

Product Name

Yellow Jacket Nest Killer

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data matrix form should be used for this purpose).



I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

4/6/16

Typed or Printed Name and Title

David H. Dawe, Agent (D.H. Dawe & Assoc.)

Fee for Service

{978801)~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: 75

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 3

Receipt No.

S-

978801

EPA File Symbol/Reg. No.

90354-E

Pin-Punch Date:

12/18/2015

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R300

Granted:

R300

Amount Due: \$ 1582.00

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: K. M. M. M.

Date: 12/21/15

Remarks:

NO data submitted FE for generic
no description/citation for product-specific
apparent want to use tech. data
Technical & Carrier only #2 data



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 21, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-512219
EPA File Symbol or Registration Number: 90354-E
Product Name: YELLOW JACKET NEST KILLER!
EPA Receipt Date: 18-Dec-2015
EPA Company Number: 90354
Company Name: 2 STAR SOLUTION INC

DAVID H. DAWE
AGENT FOR: 2 STAR SOLUTION INC
D.H. DAWE & ASSOCIATES, LLC
16844 FOUR SEASONS DR.
DUMFRIES, VA 22025

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R300
NEW PRODUCT;OR SIMILAR COMBINATION PRODUCT (ALREADY REGISTERED) TO AN IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT;REGISTERED SOURCE OF ACTIVE INGREDIENT;NO DATA REVIEW ON ACUTE TOXICITY, EFFICACY OR CRP - ONLY PRODUCT CHEMISTRY DATA;CITE-ALL DATA CITATION, OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA, OR APPLICANT SUBMITS SPECIFIC AUTHORIZATION LETTER FROM DATA OWNER;CATEGORY ALSO INCLUDES 100% RE-PACKAGE OF REGISTERED END-USE OR MANUFACTURING-USE PRODUCT THAT REQUIRES NO DATA SUBMISSION NOR DATA MATRIX;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff

Information Technology & Resources Management Division

David H. Dawe

From: Rick Matthews [REDACTED]
Sent: Tuesday, December 15, 2015 10:53 AM
To: Dave Dawe
Subject: Fwd: [FWD: Pay.gov Payment Confirmation: PRIA Service Fees]

Hi Dave
PRIA fee receipt below.
Regards,

Rick Matthews

2 Star Solutions Inc.
970 Peachtree Ind. Blvd.
Suite 100
Suwanee, GA 30024

----- Original Message -----

Subject: [Pay.gov](#) Payment Confirmation: PRIA Service Fees
From: notification@pay.gov
Date: Tue, December 15, 2015 8:48 am
To: rick@2StarSolutions.com

Your payment has been submitted to [Pay.gov](#) and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
[Pay.gov](#) Tracking ID: 25OTIQT
Agency Tracking ID: 74924537866
Transaction Type: Sale
Transaction Date: 12/15/2015 10:48:24 AM EST

Account Holder Name: Rick Matthews

Transaction Amount: \$396.00
Card Type: Visa
Card Number: *****8106

Registration Number:
Company Name: 2 Star Solutions Inc
Company Number: 90354-X
Action Code: R300

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



Receipt for Section 3

S: 978801

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Print Letter

Application Type: New Registration

Fee For Service: ☒ Yes ☐ No

Enter More Information

Billable: ☒ Yes ☐ No

Tracking

Company: 90354 2 STAR SOLUTION INC

V

Risk Manager: Registration Division, Risk Management Team 3

Product #: 90354-E Product Name: YELLOW JACKET NEST KILLER

Overseer:

Me Too
Section3:

Me Too Product
Name:

Application Date: 16-Dec-2015



OPP Rec'd Date: 18-Dec-2015



Front End Date: 18-Dec-2015



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Content

Study

CSF

View/Edit

Receipt Description:

NEW REGISTRATION WITH STUDIES

New Ingredient

Request Date:

New Ingredient

Resubmit Date:

Form A



Signature Date:

Form B



Signature Date:

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 12-18-15

Experts In-Processing Signature: B.B.

Date 12-21-15 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>90354-E</u>		EPA Receipt Date: <u>12-18-15</u>								
Items for Review				Yes	No	N/A*				
1	Application Form (EPA Form 8570-1) signed & complete including package type			X						
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X						
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td style="text-align: center;">X</td> <td></td> </tr> </table>	yes	no	X				
yes	no									
X										
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)				X					
	Certificate and data matrix consistent									
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no									
	If applicable, is there a letter of Authorization for exclusive use only.									
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X						
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)				X					
5	a) Selective Method (Fee category experts use)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no									
	b) Cite-All (Fee category experts use)									
	c) Applicant owns all data (Fee category experts use)									
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X						
7	Is the data package consistent with PR Notice 86-5			X						
8	Notice of Filing included with petitions					X				

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

Documentation: Fail

- The Certification with Respect to Citation of Data form and Data Matrix are missing. *See e-mail*

Inerts: Pass

- Inerts Approved for Non-Food Use.

11-3: Pass

MRID - 497972

Status: Fail

• Rej. letter on (4;) T.J. 12/21/15

Jackson, Tracy

From: David H. Dawe <dhdawe@dhdawe.com>
Sent: Thursday, December 31, 2015 10:33 AM
To: Jackson, Tracy
Subject: RE: Application Reg# 90354-E

Tracy,

As per our conversation, I will be happy to supply a data matrix to the PM first thing next week if necessary. Please request that she let me know if it is required.

Regarding the Certification with Respect to Citation of Data form, according to the form if the product is a 100% repack then that form is not required – and this is a 100% repack.

Thanks .

Happy New Year.

Dave

From: Jackson, Tracy [mailto:jackson.tracy@epa.gov]
Sent: Thursday, December 31, 2015 8:17 AM
To: David H. Dawe <dhdawe@dhdawe.com>
Subject: FW: Application Reg# 90354-E

Dear Mr. Dawe,

The preliminary review of this application has to be completed by noon today 12/31/15. If you are not able to send the forms to me by that time, you can send them to the PM.

Thank You

Tracy Jackson
EPA Contractor
703-308-7227
2777 S. Crystal Drive
Arlington, VA 22202

From: Jackson, Tracy
Sent: Tuesday, December 29, 2015 2:56 PM
To: 'David H. Dawe' <dhdawe@dhdawe.com>
Subject: Application Reg# 90354-E

Dear Mr. Dawe,

I am contacting you regarding your submission in support of **Yellow Jacket Nest Killer! (90354-E)**. A Data Matrix and the Certification with Respect to Citation of Data form is required with this submission.

Please send forms to jackson.tracy@epa.gov

Thank You

Tracy Jackson
EPA Contractor
703-308-7227
2777 S. Crystal Drive
Arlington, VA 22202

Jackson, Tracy

From: Jackson, Tracy
Sent: Thursday, December 31, 2015 8:17 AM
To: 'David H. Dawe'
Subject: FW: Application Reg# 90354-E

Dear Mr. Dawe,

The preliminary review of this application has to be completed by noon today 12/31/15. If you are not able to send the forms to me by that time, you can send them to the PM.

Thank You

Tracy Jackson
EPA Contractor
703-308-7227
2777 S. Crystal Drive
Arlington, VA 22202

From: Jackson, Tracy
Sent: Tuesday, December 29, 2015 2:56 PM
To: 'David H. Dawe' <dhdawe@dhdawe.com>
Subject: Application Reg# 90354-E

Dear Mr. Dawe,

I am contacting you regarding your submission in support of **Yellow Jacket Nest Killer! (90354-E)**. A Data Matrix and the Certification with Respect to Citation of Data form is required with this submission.

Please send forms to jackson.tracy@epa.gov

Thank You

Tracy Jackson
EPA Contractor
703-308-7227
2777 S. Crystal Drive
Arlington, VA 22202

Jackson, Tracy

From: Jackson, Tracy
Sent: Tuesday, December 29, 2015 2:56 PM
To: 'David H. Dawe'
Subject: Application Reg# 90354-E

Dear Mr. Dawe,

I am contacting you regarding your submission in support of **Yellow Jacket Nest Killer! (90354-E)**. A Data Matrix and the Certification with Respect to Citation of Data form is required with this submission.

Please send forms to jackson.tracy@epa.gov

Thank You

Tracy Jackson
EPA Contractor
703-308-7227
2777 S. Crystal Drive
Arlington, VA 22202



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Tim Ciarlo, M.S., Entomologist

From: Dee Colby, Ph.D., Entomologist

Secondary Review: Pesticide Efficacy Review Committee (PERC)

Date: 23-May-2017

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

THIS DER DOES CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 439032

Decision no.: 512219

Submission no: 984341

Action code: R320

Product Name: Yellow Jacket Nest Killer!

EPA Reg. No or File Symbol: 90354-E

Formulation Type: bait

Ingredients statement from the label with PC codes included:

Fipronil (9.1%) PC: 129121

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m² or mg/cm² or mg/kg body weight as appropriate): Put 6-8 drops of 0.025% fipronil per bait station with four bait stations per 10,000 ft².

Use Patterns: Outdoor bait stations (hanging) to kill yellow jacket colonies/nests; 4 baits stations per 10,000 ft² (100'x100').

I. Action Requested: The registrant submitted for review a rebuttal to a previous efficacy review dated December 27, 2016 (DP432821) that rejected efficacy claims against yellow jackets, yellow jacket wasps, wasps, and nests.

II. Background: The registrant submitted one MRID (49797201), specific to the product, to support kills claims for yellow jackets, yellow jacket wasps, wasps and nests. The registrant is rebutting recommendations in the previous review to reject claims that suggest efficacy against requested public health pest(s) and nests. An efficacy review dated June 18, 2015 (DP 425700; RDEFFICACY 90354-R 20150618; MRID 49550701) was conducted previously for a prototype of this product and was found deficient during the technical screen for not being product specific, not including a choice test or controls when testing the bait stations.

III. Rebuttal Points and Agency Responses:

Registrant Rebuttal Point 1: "No pretreatment observations were recorded."

Agency Response to Rebuttal Point 1: Though there is no indication in the study that observations of yellow jacket activity were conducted [REDACTED] the statement that the Registrant provided in the rebuttal addresses that deficiency. Typically, pretreatment assessments are indicated in submitted studies as having occurred prior to treatment application.

Registrant Rebuttal Point 2: "Yellow jackets consumed both fipronil treated and untreated baits equally, although no statistical data was presented."

Agency Response to Rebuttal Point 2: In a previous review dated June 18, 2015 (DP 425700; RDEFFICACY 90354-R 20150618; MRID 49550701), efficacy data were found to be deficient for not including a choice test or controls when testing the bait stations. While the Agency does not agree with the Registrant's justification that [REDACTED]

it was not however, a significant point of contention for considering the study unacceptable to support product performance.

Registrant Rebuttal Point 3: "MRID is unacceptable to support kills the nest of yellow jacket wasps"

Agency Response to Rebuttal Point 3: While the study shows that *Vespula* spp. subterranean nest activity decreases to 0 during treatment with bait stations containing 0.025% fipronil treated bait, the study as submitted, did not provide enough information and/or scientific evidence for the EPA to confirm that the data support efficacious levels of product performance for kills claims for yellow jackets, yellow jacket wasps, wasps, and/or nest kill claims. Stating that nests exposed to the proposed product [REDACTED] without excavation/dissection and confirmation of complete colony kill relies on an assumption of efficacy rather than evidence. The main deficiency has to do with information pertaining to the excavated nests. The number of excavated nests (n = 2) is unacceptably low. For kills claims for hive/nest/colony, we prefer to see data on at least six nests per treatment with a minimum of four excavated/dissected nests to confirm nest-level mortality. While the submitted study was deficient in identifying which nests were excavated or at what length of time after bait stations were removed that excavations took place, the Registrant did identify, in the rebuttal, which of the nests were excavated and the date of the excavations. The two excavated nests were located at a single location and were two of the nests with low nest activity. Four out of seven nests had very low numbers of individuals at the nest entrances "at the onset of the study". The two nests were excavated three days after the last assessment of nest activity. Lastly, we prefer that submitted studies include reports/descriptions of the effect of treatment on colony health, such as, any observed mortality, live adults but not foraging, no observed feeding, etc. in the excavated nests. No description was provided for the two nests in the rebuttal.

Registrant Rebuttal Point 4: Only two nests were excavated to show no nest activity. The nests were located at one site. Other nests were not excavated because of their locations.

Agency Response to Rebuttal Point 4: As the registrant brought to our attention above, only two (not three as reported in the MRID) of the 7 subterranean nests were excavated. This number of excavated nests is unacceptably low. For kills claims for hive/nest/colony, we prefer to see data on at least six nests per treatment with a minimum of four excavated/dissected to confirm nest-level mortality. The submitted study was deficient in identifying which nests were excavated or at what length of time after bait stations were removed that excavations took place. The time since zero activity at nest entrances to when excavations were conducted should correspond to the most recent labeled time for nest kill claims (i.e. 3 days) for consumer safety when approaching a nest. The submitted study does not include any report/description of colony death (or live adults) in the excavated nests. Also, as the registrant mentioned previously, excavated nests can contain live adults after 7 days. Because observations ceased at the point of zero activity at nest entrances, there was no possibility to verify if a resurgence of nest activity would occur. The registrant's years of experience are not in question, but acceptance of a study without evidence to support it would be inappropriate.

Registrant Rebuttal Point 5: Agency assumes that more bait stations were placed on some sites because of greater yellow jacket activity at those sites.

Agency Response to Rebuttal Point 5: The square footage at each site should have been included to determine the amount of fipronil that should have been used at each site and how many bait stations should have been used based on label DFU. However, the study did not include the size of each site and the Registrant has not provided that information in the rebuttal. The label DFU state, "Typically, you will need 4 Bait Stations for every 10,000 sq.ft. of area or more." The lowest labeled rate should be tested, and because we do not know the area of each site we cannot accurately calculate the application rate. Deviations in protocol should be included in the study. The study, as conducted and reported, still does not provide the information necessary to support product performance at the level claimed.

Registrant Rebuttal Point 6: "The proposed label DFU states to replace bait for 5 consecutive days, some study sites received bait for 6 days."

Agency Response to Rebuttal Point 6: As mentioned within the review, data show that some study sites (Sites 2 and 4) received fresh bait on six occasions, not five. No bait was provided during the rain-out. Even though it could take up to seven days for the colonies to die or abandon the nest, the proposed label DFU states to replace bait every morning for five consecutive days. If additional product application is required for efficacious results, then label DFU should reflect the amount of product (i.e. baiting events) needed to support product performance at the level claimed.

Registrant Rebuttal Point 7: "The Conclusions section of the study refers to a four-day training period for yellowjackets to find bait stations."

Agency Response to Rebuttal Point 7: The conclusions of this MRID 49797201 were copied from the conclusions of a previously submitted study (MRID 49550701), which is why the Efficacy Reviewer thought that three nests had been excavated and that a four day “training” period was included in the study. The Agency acknowledges that the training period should not have been included in this application.

Registrant Rebuttal Point 8: “No aerial nests were tested.”

Agency Response to Rebuttal Point 8: The Agency reviewed all information provided with MRID 497897201. Any additional/new data would have to come in for review as a new submission. While the submitted product label does not have claims for control of aerial nests, it does however have generic claims for kill of yellow jackets and wasps, “even if you do not know where the nest is located.” Label DFU also suggest hanging bait stations from a tree branch. If there is a new submission for the proposed product, either a more specific claim for subterranean nests only would need to be included on the label or acceptable data would need to be submitted to support *Polistes* spp. and *Dolichovespula maculata*.

IV. EXECUTIVE DATA SUMMARY:

(A) The information provided by the Registrant in the rebuttal to address some of the deficiencies noted in the Efficacy Review (27-December-2016), along with the submitted study (MRID 49797201) which shows that *Vespula* spp. subterranean nest activity decreases to 0 at the nest entrance during treatment with bait stations containing 0.025% fipronil treated bait, is **supplemental** to support label claims for yellow jackets and subterranean yellow jacket nests but not sufficient to support kills claims for yellowjackets, wasps, and/or nest kill claims alone. Data provided in the rebuttal, such as descriptions of nest locations and why additional bait stations were added on some of the sites after the study was underway, address some of the deficiencies noted in the efficacy review, but not all. The main deficiency was that the number of excavated nests (n = 2) is unacceptably low. For kills claims for hive/nest/colony, we prefer to see data on at least six nests per treatment with a minimum of four excavated/dissected nests to confirm nest-level mortality. In addition, we prefer that submitted studies include reports/descriptions of the effect of treatment on colony health, such as observed mortality, live adults but not foraging, absence of feeding behavior, etc., in the excavated nests.

In an effort to provide weight of evidence to support this product’s performance, the Efficacy Reviewer considered information that was previously submitted for review of this product. MRID 49797201 dated December 10, 2015 is not suitable for bridging to the proposed product, because the prototype bait stations tested in that study included an attractant lure and a prebaiting component, which are not part of the proposed product. In the document titled, Administrative Materials Volume 1 of 2 dated December 15, 2015 (no MRID), the Registrant described the multi-year process of product development based on field tests. This background information provides evidence for use of 0.025% fipronil to reduce the number of foragers collected at monitoring stations on study sites by > 90% pre-treatment levels for up to 3 weeks. [Note: No data pertaining to activity at nests or nest kill was provided in the document.] In the Reviewer’s scientific opinion, the information provided in MRID 49797201 for the proposed product along with the reduction of forager numbers noted product development trials described in the Administrative Materials Volume 1 of 2 dated December 15, 2015 (no MRID), would support a kills only claim for yellowjacket foragers.

V. LABEL RECOMMENDATIONS:

- (1) All Directions for Use as a bait station to treat nests should be deleted. See attached label additional changes.
- (2) The following marketing claims are acceptable:
 - Kills only claims for yellowjackets/yellow jackets.
- (3) The following marketing claims are unacceptable:
 - claims suggesting efficacy against nests

- nest killer

(4) The following MRIDs should be removed from the data matrix, as they are classified as “unacceptable” to support the product: n/a

Note to the PM: The Efficacy Review for MRID 49797201 has been promoted from unacceptable to supplemental based on the additional information provided by the Registrant in their rebuttal document. Two other documents were viewed to see if further support for the product’s performance may have been provided but were not part of the review. Neither document contained information specific to the proposed product. However, in the Reviewer’s professional opinion, information provided in the document titled, Administrative Materials Volume 1 of 2 dated December 15, 2015 (no MRID) and the data in MRID 49797201 would support a kills claim for yellow jacket foragers. Nest kill claims are not supported.

(FRONT)

Yellow Jacket Nest Killer!

~~KILLS THE NEST~~

Even if you don't know where it is!

~~PROVEN TO WORK!~~

4 Bait Stations Included

KEEP OUT OF REACH OF CHILDREN

CAUTION (PRECAUCION)

See back panel and enclosed booklet for additional First Aid.

(Note: If you do not understand the label, find someone to explain it in detail.)

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.

Directions for use and Precautionary Statements on Back Panel

Active Ingredient:

Fipronil* 9.1%

Other Ingredients90.9%

Total 100.00%

*(5-amino-1-(2,6-dichloro-4-(trifluoromethyl) phenyl)-4-(1,R,S)
(trifluoromethyl) sulfinyl)-1-H-pyrazole-3-carbonitrile

Net contents: 0.3ml (0.01 oz.)

EPA Reg. No. 90354-X

EPA Est. No. 90354-GA-001

(TOP and BACK)

FIRST AID

If Swallowed: Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

If in Eye(s): Hold eye open and rinse gently with water for 15 to 20 minutes. If wearing contacts, rinse eye for 5 minutes, remove contact and continue rinsing. Call a Poison Control Center or doctor immediately for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a Poison Control Center or doctor for treatment advice.

If Inhaled: Move person to fresh air. If person is not breathing call 911 or ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a Poison Control Center or doctor for treatment advice.

Note to Physician: There is no specific antidote. All treatment should be based on observed signs and symptoms of distress in the patient. Overexposure to materials other than this product may have occurred. In severe cases of overexposure by oral ingestion, lethargy, muscle tremors, and in extreme cases, possibly convulsions may occur.

Have the product container or label with you when calling a Poison Control Center or doctor, or going for medical treatment. You may also contact the Poison Help Line at 1-800-222-1222 for treatment advice.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Caution: Harmful if swallowed, absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash any contaminated clothing.

NOTE: If you are allergic to bee or wasp stings, do not personally use this product.

Have someone other than yourself handle and maintain the Yellow Jacket Nest Killer!

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Non-refillable Container: Do not reuse or refill this container. Dispose of in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

ENVIRONMENTAL HAZARDS

The pesticide contained in the bottle is extremely toxic to fish and other aquatic invertebrates. Do not discharge this product into lakes, streams, ponds, estuaries, oceans or other waters or sewage systems. Do not use within 25 feet of any body of water.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling. Read entire label before using this product. See enclosed instructions for Bait Station and complete Directions for Use.

(LEFT SIDE)

FINALLY! Now you have a proven, easy-to-use product that is proven to not only kill yellow jacket wasps, but it will kill them in their nest as well **even if you do not know where the nest is located.**

Simply hang each Yellow Jacket Nest Killer! Bait Station with treated bait inside and replace the bait daily for 5 consecutive days. **It's that easy!**

Bait Stations are made of transparent plastic that hangs easily from a tree branch or other hanging location with the included twist ties.

To effectively kill yellow jackets and the nest, use multiple Bait Stations.

- Bait Stations should be placed 60-75 feet apart.
- 1 bait station kit contains 4 bait stations.
- **Use 4 bait stations for every 10,000 sq. ft. (100'x100') of area for best results.**

@2014 2 Star Solutions Inc. All rights reserved

RIGHT SIDE

PROVEN TO WORK! Everything Included!

The **YELLOW JACKET NEST KILLER!** Is the easiest way to solve your yellow jacket problem...~~because it's a proven product that kills the nest...even if you do not know where the nest is located.~~ This way you do not have to kill or "trap" them one at a time, but all at once in the shortest time possible.

CAUTION: If you are allergic to bee or wasps stings do not personally use this product. Have someone other than yourself hang and maintain the Bait Station.

U.S. Patent Pending

Assembled in the U.S.A.

EPA Reg. No. 90354-Pending EPA Est. No. 90354-GA-001

SOLD BY:

2 Star Solutions Inc.

970 Peachtree Ind. Blvd.

LOGO

Suite 100

Suwanee, GA 30024

For more information visit:

YellowJacketNestKiller.com

Questions or Comments? Call 1-888-448-1669 Batch No. _____

"Infection Insert for Yellow Jacket Nest Killer"

YELLOW JACKET NEST KILLER!™ allow user to kill the yellow jacket nest without the dangers of applying an oil or powder pesticide to the nest. Stings from wasps can be very painful and in some cases life threatening. The risk of being stung by a wasp is reduced with the proper use of this product.

YELLOW JACKET NEST KILLER!™ is not a trapping device. This unique "Bait Station" is designed to attract yellow jacket wasps and allow them to enter and feed on the pesticide-treated bait. The wasp will exit the Bait Station and take the treated bait to its nest to feed the larvae. Research has shown that the entire wasp colony will either die or abandon the nest within 3 to 7 days. Sprays and traps can be used to get rid of some wasps, although wasps will not leave your property until you kill their nest. Best of all, you do not need to know where the nest is located.

Active Ingredient:	Fipronil.....	9.1%	* (5-amino-1-(2,6-dichloro-4-(trifluoromethyl) phenyl)-4-(1,R,S) (trifluoromethyl) sulfinyl)-1-H-pyrazole-3-carbonitrile
Other Ingredients.....		90.9%	
Total.....		100.0%	

STOP! READ ENTIRE DIRECTIONS BEFORE USE

Keep Out of Reach of Children

CAUTION (PRECAUCION)

FIRST AID
If Swallowed: Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.
If in Eyes: Hold eye open and rinse gently with water for 15 to 20 minutes. If wearing contacts, rinse eye for 5 minutes, remove contact and continue rinsing. Call a Poison Control Center or doctor immediately for treatment advice.
If on Skin of Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.
If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for treatment advice.
Note to Physician: There is no specific antidote. All treatment should be based on observed signs and symptoms of distress in the patient. Overexposure to materials other than this product may have occurred. In severe cases of overexposure by oral ingestion, lethargy, muscle tremors and, in extreme cases, possibly convulsions may occur.
Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment. You may also contact the Poison Help Line at 1-800-222-1222 for treatment advice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if swallowed, absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse.

PRECAUTION. Wasp, hornet and yellow jacket stings can be life threatening to persons who are allergic to the venom. People who develop hives, difficulty breathing or swallowing, wheezing or similar symptoms of allergic reaction should seek medical attention immediately if stung by a wasp.

ENVIRONMENTAL HAZARDS

The insecticide contained in the Bait Station is extremely toxic to fish and other aquatic invertebrates. Do not discharge this product into lakes, streams, ponds, estuaries, oceans, or other waters or sewage systems. Do not contaminate water by disposal of waste. Do not use this product within 25 feet of any body of water.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product inconsistent with its labeling. For residential and commercial use. For non-food use only. **Do not hang bait station or replace bait if you are allergic to wasp, hornet or yellow jacket stings.**

INITIAL SET-UP: DAY 1

1. Open Bait Station and remove all contents.
2. Remove empty insecticide bottle and fill with clean water to fill line marked on the bottle. Open pesticide blister package by bending back and forth at the scored line at the top of the bottle imprint. Carefully hold the blister packaging on the flat areas next to the top of the bottle imprint and tear off the top of the blister package. Squeeze entire contents into the water bottle.
3. Remove four (4) bait trays, bait food packet and spoon. Add one (1) level spoonful of bait food to each of the bait trays (3-4 cubes). Add one (1) level spoonful of water to bait tray. Wait 1-2 minutes for bait to absorb the water. Drain off any unabsorbed water.
4. NOW, Shake Insecticide bottle well (minimum of 30 sec.). Add 2 drops of diluted insecticide to each cube of bait. **IMPORTANT:** More than 8 drops will REPEL wasps. **NOTE:** Wasps will not eat spoiled meat. **For best results,** replace bait trays and bait every morning for 5 consecutive days.
5. Insert loaded Bait Trays into Bait Tray receptacles - as shown in right diagram B.
6. Close the Bait Stations and press your fingers together on the button snap closures (C).
7. Take the loaded Bait Stations and Twist Ties outdoors to hanging locations.
8. Attach the Twist Tie to the hanger opening at the top of each Bait Station. Wrap the Twist Tie at least two (2) times around itself for secure attachment.
9. Hang the Bait Stations a minimum of 20 feet away from any known nest. Keep the Bait Stations away from your house or any outdoor living area.
10. Hang the Bait Stations in SHADED AREAS for best results. **NOTE:** Using the Twist Tie, hang the Bait Station from a tree branch (or other hanging location) high enough from the ground that it cannot be reached by family pets or children.
11. Wash hands thoroughly with soap and water immediately after handling Bait Station.

DAILY OPERATION: DAY 2 and beyond

For best results, perform the following steps every morning after Day 1:

1. Check Bait Station for wasps. **If wasps are present, do not attempt to change the bait.**
2. If wasps are not present, remove the Bait Station from the Twist Tie.
3. Open Bait Station and remove used Bait Tray. Use a NEW Bait Tray and add 1 level spoonful of bait food and 1 level spoonful of water. Wait 1-2 minutes for bait to absorb the water. **NOW, Shake insecticide bottle well.** Then add 6-8 drops of insecticide to cover the Bait. **IMPORTANT:** More than 8 drops will REPEL wasps. **NOTE:** Wasps will not eat spoiled meat. **For best results,** replace bait tray and bait every morning for 5 consecutive days.
4. Re-hang the Bait Station with the Twist Tie from the bait station hanger opening.
5. Dispose of the used Bait Tray and bait into your trash receptacle.
6. Wash hands thoroughly with soap and water immediately after re-hanging the Bait Station and after handling the used Bait Trays.

BAIT STATION PLACEMENT

1. Hang Bait Stations in shaded areas away from house and outdoor living areas.
2. Bait Stations should be placed 60 to 75 feet apart. Typically, you will need 4 Bait Stations for every 10,000 sq. ft. of area or more.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide is in violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional office for guidance.

Container Disposal: Nonrefillable Container: Do not reuse or refill this container. Dispose of in a sanitary landfill, or by incineration, or by other procedures approved by the state and local authorities.

WARRANTY STATEMENT

2 STAR SOLUTIONS, Inc. warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for purposes stated on such label only when used in accordance with directions under normal use conditions. The exclusive remedy of any buyer or user of this product for any and all losses, injuries, or damage resulting from or in any way arising from the use, handling, or application of this product, whether in contract, warranty, tort, negligence, strict liability, or otherwise, shall be damages not exceeding the purchase price paid for this product or, at 2 Star Solutions, Inc.'s option, the replacement of this product.

NET CONTENTS: One (1) blister pack of insecticide 0.3 ml (0.01 oz.)
One (1) packet of freeze-dried chicken (1.12 oz.)

SOLD BY: 2 Star Solutions, Inc.

970 Peachtree Industrial Blvd., Suite 100, Suwanee, GA 30024 1-888-448-1669

EPA Reg. No. 090354-Pending EPA EST. No. 90354-GA-001 U.S. Patent Pending



Bait Station - OPENED A

Bait Tray - 20 Total

Twist Tie 4 Total

Bait Food Packet

Oxygen Absorber

Spoon

Insecticide Dropper Bottle

Insecticide Blister Pack

For more information about Yellow Jacket Wasps, visit: YellowJacketNestKiller.com



Yellow Jacket Nest Killer!

Instructions Instrucciones

MADE IN THE U.S.A.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Tim Ciarlo, M.S., Entomologist

From: Dee Colby, Ph.D., Entomologist

Secondary Review: Jennifer Saunders, Ph.D., Senior Entomologist

Date: 27-December-2016

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

THIS DER DOES CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 432821

Decision no.: 512219

Submission no: 984341

Action code: R320

Product Name: Yellow Jacket Nest Killer!

EPA Reg. No or File Symbol: 90354-E

Formulation Type: bait

Ingredients statement from the label with PC codes included:

Fipronil (9.1%)

PC: 129121

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m² or mg/cm² or mg/kg body weight as appropriate): Put 6-8 drops of 0.025% fipronil per bait station with four bait stations per 10,000 ft².

Use Patterns: Outdoor bait stations (hanging) to kill yellow jacket colonies/nests; 4 baits stations per 10,000 ft² (100'x100').

I. Action Requested: Reviewer requested a product efficacy review of the submitted MRID to determine if the data support product use and kills claims for yellow jackets and yellow jacket nests.

II. Background: Registrant is proposing an R320 for registration of a new product requiring data review to support kills claims for yellow jackets, yellow jacket wasps, wasps and nest claims. One new MRID (49797201), specific to the product, was submitted to support product efficacy claims. An efficacy review dated June 18, 2015 (DP 425700; RDEFFICACY 90354-R 20150618; MRID 49550701) was conducted previously for a prototype of this product and was found deficient during the technical screen for not being product specific and for not including a choice test or controls when testing the bait stations.

III. MRID Summary:

49797201. Matthews, R. and D.H. Dawe (2015) Efficacy studies on yellow jackets (*Vespula* sp.) with 2 Star Solutions, Inc. bait stations in residential areas.

(1) non-GLP

(2) **Methods:** This is a field study. Seven, subterranean *Vespula* spp. nests were located at five residential sites in several towns in Georgia during August 2015. Bait trays for choice tests were prepared with two trays of rehydrated chicken, one untreated and one treated with 8 drops of 0.025% fipronil. Both bait trays were placed into a single transparent hanging container to provide a choice test for foraging yellow jackets. Containers were hung in shaded locations on the sites; height was not specified. Two to six containers were hung per site at ~ 60 ft apart. Determination for the number of containers per site was not specified. Numbers of yellow jacket foragers at nest entrances were recorded for 2 minutes each day over the course of the study; no pretreatment observations were conducted/recorded. At four of the seven nests it was determined that additional bait stations (i.e., containers) were needed, based on nest and trap observations, so additional containers were added during days 2-4 of the study depending on the site. Bait trays were replaced daily for 3-6 days depending on nest activity at each nest entrance. Containers were removed and observations ceased when nest activity reached 0. Two of the sites had 2 nests present, so containers were removed from each of those sites when activity at both nests on a site was 0. Three of the seven nests were excavated to check for internal activity. It was not stated which nests were excavated and at what point after baiting had stopped the nests were excavated. The amount of bait remaining in each tray was recorded daily, along with nest activity and weather conditions. There were no control nests in this study.

(3) **Results:** Numbers of foragers at 3 of the 7 nests were very low throughout the study (i.e., less than 10 individuals/observation). Yellow jackets consumed both fipronil-treated and untreated baits equally, although no statistical data were presented. Authors stated that the three excavated nests showed no activity. The number of yellow jackets entering and leaving nests reached 0 after 3-6 days of treatment with fipronil baits depending on the site.

(4) **Conclusion:** This MRID is **unacceptable** to support kills the nest claims and/or kills yellow jacket wasps. Three of the 7 subterranean nests were excavated to “check internal activity” and “no activity was observed within the nest”, but there was no report/description of colony death in the excavated nests. If the lack of activity observed within the excavated nests refers to evidence that the colony had abandoned the nest, as the label states, nests may be abandoned, then abandoned nests would not support kills the nest or “nest killer” claims. Also, the study did not identify which nests were excavated or at what length of time after bait stations were removed that excavations took place. The point at which excavations took place would have been useful information since there was no possibility for verification of a resurgence of nest activity because observations ceased at the point of zero nest activity.

While the Agency prefers that proper controls be included in an efficacy study, the Reviewer realizes that suitable numbers of subterranean *Vespula* nests may be difficult to locate and that controls were not necessary for statistical comparison. However, due to the high degree of variability in sizes of nests (based on activity at nest entrances) used in this study, species identification and observation of activity at bait stations should have been included. Four of the 7 nests showed very low numbers for activity throughout the study compared to the other three nests.

Also, the square footage at each site should have been included to determine the amount of fipronil used at each site and how many bait stations should have been used based on label DFU. Label DFU state to use 4 bait stations per 10,000 ft². There were different numbers of bait stations used at different sites within the study, from 2 – 6 bait stations and bait station numbers were increased at days 2-4 on four of the sites “to provide more feeding locations”, not due to square footage. However, two of the sites (i.e., Quail Point Run and Vinings Lane) receiving additional bait stations had < 10 individuals at each observation compared to other sites with upwards of 9x higher numbers, so the numbers of individuals observed at nest entrances don’t appear to support the need for additional bait stations. In addition, while the proposed label DFU state to replace bait for 5 consecutive days, some study sites received bait for 6 days. Elsewhere on the label it also states that research has shown it could take up to 7 days for colonies to die or abandon the nest. There should be congruency between label DFU, claims and what the data supports for labeling.

- talk to Dec
- rebuttal
10 visits

The Conclusions section of the study refers to a four-day training period for yellow jackets to find bait stations. There was no indication in the study methods nor on the label that it is necessary to train yellow jackets to visit the bait stations prior to the addition of fipronil.

No aerial nests were tested, and the proposed label does not specify for subterranean nests only. The label refers to yellow jacket, yellow jacket wasps, wasps, yellow jacket nests and wasp colonies; therefore, *Polistes* and *Dolichovespula maculata* should be tested as well.

IV. EXECUTIVE DATA SUMMARY:

(A) While the study shows that *Vespula* spp. subterranean nest activity decreases to 0 during treatment with bait stations containing 0.025% fipronil treated bait, it is not sufficient for kills claims for yellow jackets, yellow jacket wasps, wasps, and/or nest kill claims.

V. LABEL RECOMMENDATIONS:

- (1) All Directions for Use as a bait station to treat nests should be deleted. This is the only use on the label.
- (2) The following marketing claims are acceptable:
 - no claims are supported on the label
- (3) The following marketing claims are unacceptable:
 - claims suggesting efficacy against yellow jackets, wasps, yellow jacket wasps and/or nests
 - nest killer
- (4) The following MRIDs should be removed from the data matrix, as they are classified as “unacceptable” to support the product: **49797201**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

10/JAN/2017

MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol 90354-E

Name of Pesticide Product: Yellow Jacket Nest Killer!
EPA File Symbol: 90354-E
DP Barcode: D432826
Decision No.: 512219
Action Code: R320
PC Code: 129121 (fipronil)

From: Eugenia McAndrew, Biologist *Eugenia McAndrew*

Through: John C. Redden, M.S., Senior Risk Assessor *JCR*
Chemistry, Inerts and Toxicology Assessment Branch
Registration Division (7505P)

To: Timothy Ciarlo, RM Team 03
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)

Applicant: 2 Star Solutions, Inc.
1954 East Bay Street
Hoshton, GA 30548

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Fipronil	9.1
<u>Other Ingredient(s):</u>	<u>90.0</u>
Total:	100.0%

ACTION REQUESTED: The Risk Manager requests a review of six acute toxicity studies submitted to support the registration of the proposed product, EPA File Symbol 90354-E.

BACKGROUND: 2 Star Solutions, Inc. has submitted six acute toxicity studies (MRID Nos. 447498-02 to -06 and 44769902) to support the registration of the proposed product, Yellow Jacket Nest Killer!, EPA File Symbol 90354-E. The submission includes a basic CSF dated December 16, 2015 which must be accepted by the CITAB Product Chemistry Team.

GLP: Yes

DEVIATIONS: Acute Oral Toxicity Study (MRID 44749802): The incorrect protocol (OECD 401: Acute Oral LD₅₀) was used for this test. Although we accepted the study in this case, our guidance is that OECD 401 is no longer an acceptable protocol. Please inform the Registrant that the preferred protocols are OECD 425: Acute Oral Toxicity-Up-and-Down Procedure and OECD 423: Acute Toxic Class.

LABELING: Based on the toxicity profile, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: 090354-00002

PRODUCT NAME: Yellow Jacket Nest Killer!

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Harmful if absorbed through skin. Harmful if inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

DATA EVALUATION RECORD

Product Reg. No.: 90354-E

Product Name: Yellow Jacket Nest Killer!

1. DP BARCODE: 432826				
2. PC CODE: 129121				
3. CURRENT DATE: January 10, 2017				
4. TEST MATERIAL (in five studies): Termidor 0.8 SC (Batch/Lot # 14STGX82; 10.2% w/w fipronil; opaque, tan liquid)				
Primary eye irritation study: Termidor 0.8 SC (Batch/Lot # 14STGX82A; 9.44% w/w fipronil; opaque, tan liquid)				
Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity / rat WIL Research Laboratories, Inc./Study #WIL-21136 January 11, 1999 OCSPP 870.1100; OECD 401	44749802	<p>LD₅₀ = 1999 mg/kg (both sexes) (95% CL of 1208 to 3311 mg/kg)</p> <p>5 of each sex were tested at three doses: 1183, 2000 or 3380 mg/kg</p> <p><u>Mortality:</u> 1183 mg/kg: 3/10 2000 mg/kg: 5/10 3380 mg/kg: 7/10</p> <p>All deaths occurred within the first week of dosing. Clinical findings were noted in all dose groups. The most common clinical signs of toxicity were abnormal excretion (decreased defecation and/or mucoid feces), various discolored areas due to discharges/excretions (described as wet and/or dried brown, clear, red and/or yellow material around the nose, mouth, facial area, forelimbs, hindlimbs, anogenital and/or urogenital area.) Also noted were hypoactivity, hypersensitivity to touch and hair loss. Single instances of scabbing</p>	III	A

		<p>on forelimbs and tremors were observed. Three animals had hair loss through study termination. All other animals recovered by day 11. One female in the 3380 mg/kg dose group lost 14% of body weight prior to death on day 7. One male in the 2000 mg/kg group lost 2.7% body weight initially but gained weight by the end of the study. Gross necropsy in the animals that died on test revealed dark red lungs in three males, ocular opacity in one animal and distended stomach in one animal. Various clear, red and/or yellow matting around the eyes, nose, mouth, forelimbs, anogenital and/or urogenital area were noted for fourteen animals. In the animals that survived to study termination, one female had hair loss along the lateral abdominal region. No other findings were noted.</p>		
<p>Acute dermal toxicity / rat WIL Research Laboratories, Inc./Study #WIL-21110 May 6, 1998 OCSP 870.1200; OECD 402</p>	44749803	<p>LD₅₀ > 2000 mg/kg (both sexes)</p> <p>All animals survived. Body weight loss was noted for nine animals during the first week of the study. All animals gained weight during the second week but three animals did not surpass initial weights. Clinical signs of toxicity included loss of appetite, decreased defecation and decreased urination. The animals recovered from these symptoms by the end of the first week of the study. Dermal irritation was observed: very slight erythema in nine animals, very slight edema in one animal and desquamation on</p>	III	A

		four animals. Three animals still exhibited very slight erythema or desquamation at study termination. No gross abnormalities were noted at necropsy.		
Acute inhalation toxicity / rat WIL Research Laboratories, Inc./Study #WIL-21139 January 29, 1999 OCSPP 870.1300; OECD 403	44749804	<p>LC₅₀ >1.7 mg/L (both sexes)</p> <p>Two exposures were tested: 1.3 mg/L and 1.7 mg/L</p> <p><u>1.3 mg/L:</u> MMAD: 7.3 µm GSD: 3.31</p> <p><u>1.7 mg/L:</u> MMAD: 2.2 µm GSD: 1.95</p> <p>All animals survived at both exposures. The only clinical sign of toxicity was labored respiration in one male and two females in the 1.7 mg/L group. All animals in both groups had slight body weight losses from day 0 to day 3 but all animals exceeded initial body weights by study termination. No gross abnormalities were observed at necropsy.</p>	III	A
Primary eye irritation / rabbit WIL Research Laboratories, Inc./Study #WIL-21112 May 13, 1998 OCSPP 870.2400; OECD 405	44769902	<p>2 males and 4 females tested</p> <p>No corneal opacity or iritis were observed. A score of 1 for conjunctival redness, chemosis and/or discharge was noted in all eyes at one hour, in two eyes at 24 hours and in one eye at 48 hours. All eyes were free of irritation by 72 hours.</p>	IV	A

Primary dermal irritation / rabbit WIL Research Laboratories, Inc./Study #WIL-21137 January 11, 1999 OCSPP 870.2500; OECD 404	44749805	PDI = 0.5 4 males and 2 females tested Very slight erythema was observed at 3/6 sites 30-60 minutes after patch removal persisting at one site through day 4. All sites were free of irritation by day 5.	IV	A
Dermal sensitization / guinea pig WIL Research Laboratories, Inc./Study #WIL-21138 January 22, 1999 OCSPP 870.2600; OECD 406	44749806	Negative Appropriate positive control provided.	--	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap



Scm



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D432824; **FILE SYMBOL No.:** 90354-E (screen); **PRODUCT NAME:** Yellow Jacket Nest Killer!; **DECISION No.:** 512219; **PC Code(s):** 129121; **ACTION CODE:** R320; **FOOD Use:** No

DATE OUT: April 20, 2016

SUBJECT: 45/90 day screen results for end use product "Yellow Jacket Nest Killer!"

FROM: Shyam Mathur, Product Chemistry Team Leader CITAB/RD (7505P)

TO: Timothy Ciarlo / Kable Davis, RM 03, I-V Branch 1 / RD (7505P)

Shyam Mathur
Kable Davis

Company Name: 2 Star Solution Incorporation

Active Ingredient(s): Fipronil (9.1%)

MRID No(s): Cited – 44769901 (All PC data cited, registrant claimed identical to Reg. No. 7969-210)

CONCLUSION:

Deficiencies: No

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

Group A: All required data cited

Group B: All required data cited.

CSF: Basic CSF (dated 12-16-2015) submitted.

PRODUCT LABEL: Submitted

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to the author of this report the corrected deficiencies in response to 10 day letter. The corrected deficiencies will be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

FEE

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP BARCODE No.: D432824; **FILE SYMBOL No.:** 90354-E; **PRODUCT NAME:** Yellow Jacket Nest Killer! **DECISION No.:** 512219; **PC Code(s):** 129121; **ACTION CODE:** R320; **FOOD Use:** No

DATE OUT: January 10, 2016

SUBJECT: End Use Product Chemistry Review
Product Name: Yellow Jacket Nest Killer!

FROM: Shyam Mathur, Ph.D
Chemistry Team Leader
CITAB/RD (7505P)

S. Mathur
01-10-17
JCR

TO: Timothy Ciarlo / Kable Davis, RM 03
I-V Branch 1 / RD (7505P)

INTRODUCTION:

The registrant has submitted an application for the registration of the new end use product "Yellow Jacket Nest Killer!". The registrant has submitted a CSF for basic formulation (dated December 16, 2015) and the product label. On the advice of the Agency, the registrant submitted the revised basic CSF (dated January 9, 2017). The registrant has claimed that the proposed product is substantially similar/identical to the registered product with Reg. No. 7969-210. The registrant has cited the supporting group A and group B product chemistry data with MRID No. 44769901. CITAB has been asked to determine the acceptability of the proposed basic CSF and the supporting product chemistry data cited and also determine similarity to the cited product.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Fipronil (9.10%)

2. Has the registrant claimed substantial similarity to a registered product?

[X] Yes; [] No; [] NA; if yes, give the registration number of the cited product: Reg. No. 7969-210

3. All of the source materials of the active ingredient are derived from registered sources: [X] Yes [] No

DP BARCODE No.: D432824; **FILE SYMBOL No.:** 90354-E; **PRODUCT NAME:** Yellow Jacket Nest Killer!; **DECISION No.:** 512219; **PC Code(s):** 129121; **ACTION CODE:** R320; **FOOD Use:** No

4. All inert ingredients have been screened by IAB and found to be approved for the proposed labeled Uses: ☒ Yes; ☐ No.

5. Confidential Statement of Formula(s):

☒ Basic - Dated: 12-16-2015; Resubmitted – Dated: 01-09-2017

☐ Alternate CSF – Dated: ; Re-submitted – Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☐ Yes; ☐ No; ☒ NA

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid Equivalent: ☐ Yes ☒ NA;

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☐ No ☒ NA

Methanol at > 4%: ☐ Yes ☐ No ☒ NA

Sodium nitrate/Sodium Nitrite ☐ Yes ☐ No ☒ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown?

☐ Yes; ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:

DP BARCODE No.: D432824; **FILE SYMBOL No.:** 90354-E; **PRODUCT NAME:** Yellow Jacket Nest Killer; **DECISION No.:** 512219; **PC Code(s):** 129121; **ACTION CODE:** R320; **FOOD Use:** No

7. Group A: Product Chemistry Data cited from Reg. No. 7969-210

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos. cited
			Yes	No		
830.1550	Product Identity & Composition		cited		N	44769901
830.1600	Description of materials used to produce the product		cited		N	44769901
830.1650	Description of formulation process		cited		N	44769901
830.1670	Discussion on the formation of impurities		cited		N	44769901
830.1700	Preliminary analysis				NA	
830.1750	Certified limits (158.350)	Standard certified limits	X		A	Revised Basic CSF dated 01-09-2017
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		cited		N	44769901

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

DP BARCODE No.: D432824; **FILE SYMBOL No.:** 90354-E; **PRODUCT NAME:** Yellow Jacket Nest Killer!; **DECISION No.:** 512219; **PC Code(s):** 129121; **ACTION CODE:** R320; **FOOD Use:** No

8. Group B: Physical-Chemical characteristics cited from Reg. No. 7969-210

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos. cited
830.6303	Physical State	Data cited	N	44769901
830.6314	Oxidation/Reduction	Data cited	N	44769901
830.6315	Flammability	Data cited	N	44769901
830.6316	Explosibility	Data cited	N	44769901
830.6317	Storage stability	Data cited	N	44769901
830.6320	Corrosion characteristics	Data cited	N	44769901
830.7000	pH	Data cited	N	44769901
830.7300	Density	Data cited	N	44769901
830.7100	Viscosity	Data cited	N	44769901

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable.

DP BARCODE No.: D432824; FILE SYMBOL No.: 90354-E; PRODUCT NAME: Yellow Jacket Nest Killer; DECISION No.: 512219; PC Code(s): 129121; ACTION CODE: R320; FOOD Use: No

CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted for the end-use product and has concluded that:

A. Substantial similarity to the cited product (Reg. No. 7969-210) from Product chemistry view point

- ☐ Similar
- ☐ Not similar, give reasons:
- ☐ Identical
- ☒ Not identical
- ☐ Not applicable

Note 1: Though the proposed & cited products contain same active ingredient Fipronil with same nominal concentration of 9.10%, since the two product contain very different inert ingredients & from different sources, two products are not considered identical.

B. Confidential Statement of formula

1. Revised Basic CSF (dated 01-09-2017)

- ☐ Acceptable
- ☒ Not Acceptable
- ☐ Not Applicable

Note 2: The revised basic CSF will be evaluated again when required group A & group B product chemistry are submitted.

2. Alternate CSF #1 (dated: 09-07-2016)

- ☐ Acceptable
- ☐ Not Acceptable
- ☒ Not Applicable

C. Group A Product Chemistry Data

- ☐ Acceptable
- ☐ Acceptable with the exception of the guideline:
- ☒ Not acceptable
- ☐ Not required
- ☒ Data cited

Note 3: Since the cited & proposed products are not identical in chemical composition, the registrant must submit required product specific group A data for the proposed product.

D. Group B Product chemistry data

- ☐ Acceptable
- ☒ Not acceptable
- ☐ Acceptable with the exception of the guidelines
- ☐ Not required
- ☒ Data cited

Note 4: Since the cited & proposed products are not identical in chemical composition, the registrant must submit required product specific group B data for the proposed product.

E. Product Label/Draft Label

Recommendations – Yes ☐; No ☒



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 24, 2016

PC Code: 129121

DP Barcode: 432832 [REDACTED]

MEMORANDUM

SUBJECT: **Fipronil:** Section 3 ecological risk and drinking water assessment for use of fipronil in bait stations for the control of yellow jackets (*Vespula spp.*)

FROM: Edward Odenkirchen, Ph.D., Senior Advisor *E.O. Odenkirchen*
Immediate Office
Environmental Fate and Effects Division (7507P)

THRU: Sujatha Sankula, Ph.D. Chief *for Sujatha, Greg Orlick 8-24-16*
Environmental Risk Branch 1
Environmental Fate and Effects Division (7507P)

TO: Timothy Ciarlo, Risk Manager Reviewer
Kable Davis, Risk Manager
Marietta Echeverria, Chief
Invertebrate-Vertebrate Branch 1
Registration Division (7505P)

The Registration Division (RD) requested the Environmental Fate and Effects Division (EFED) to conduct an ecological risk and drinking water assessment to support a FIFRA Section 3 regulatory decision concerning the use of fipronil ([REDACTED] 2-Star Solution's Yellow-Jacket Nest Killer) for the control of yellow jackets.

Description of Use

The referenced products are packaged as bait stations (bait station structure, fipronil solution, and bait material) [REDACTED]

[REDACTED] The bait material is meat based and is said to be attractive to yellow jackets [REDACTED] (the Yellow-Jacket Nest Killer label does not mention attractiveness to honeybees). The bait boxes are either small flexible plastic structures [REDACTED] neither of which are certified pet proof. While the labels mention deploying the stations from strings or wires attached to tree limbs, stakes, fence posts, or poles, there is no requirement that they be deployed in a manner where scavenging wildlife cannot access them.

The labels include the following application instructions (*paraphrased*):

1. Application rate:

[REDACTED]

[REDACTED]

[REDACTED]

Yellow-Jacket Nest Killer:

Four bait stations /10,000 ft²

Entire contents of fipronil solution for four bait stations is 0.3 ml

0.3 ml solution * 1 g/ml (assumed density) * 0.091 (g fipronil/g solution) = 27.3 mg fipronil

27.3 mg fipronil /10,000 ft² * 43,560 ft²/acre = **119 mg fipronil/acre**

(NOTE: the language on Yellow-Jacket Nest Killer proposed label is not clear that 4 stations per 10,000 ft² is the maximum. For this risk assessment to be valid, modifications to the label to this effect must be in place.)

2. Reapplication Interval:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Yellow-Jacket Nest Killer:

The label indicates that the entire contents of a single package (containing 4 bait stations and a 0.3 ml solution of fipronil) would be used over approximately five days. However, the label is silent regarding the number of repeated package placements in a given year.

(NOTE: for the purposes of this risk assessment the use of the total package contents is assumed to be used on an acre, once per year. The labels on all products should be clarified in this regard in order for this risk assessment to be valid. An E-mail outlining this label issue was submitted to RD on March 31, 2015 yet no change to the label was submitted in response.)

Conceptual Model for Risk Assessment

In an email to RD dated March 31, 2015 EFED reviewers outlined the approach to the initially reviewed labels for these products as they relate to the assumptions of complete exposure pathways to non-target receptors. The email placed these labels in comparison with the situation encountered in a previous experimental Use Permit of the baits in Hawaii, comparing and contrasting the expected conditions of use and the attendant exposure pathways considered to be

complete. Because nothing on the labels has significantly changed regarding the description of allowable use the conceptual model is still valid and is captured from that document below:

EFED previously evaluated this use in connection with an experimental use permit for fipronil to control western yellow jackets in Hawaii Volcanoes National Park. That review made a finding of no complete exposure pathways for non-target terrestrial invertebrates. In this previous action, contaminated /eradicated insect nests were to be excavated and removed, preventing materials from entering surface and ground water and from entering terrestrial vertebrate food chains.

In contrast, under the new use, there is no provision for yellow jacket nest removal. Consequently, there are potential complete exposure pathways to surface and ground waters and to terrestrial vertebrates consuming the remains of yellow jacket nests. The available information accompanying the application also indicates that, though infrequent, non-target terrestrial invertebrates can gain access to the bait station contents.

EFED expects that a risk assessment supporting Section 3 registration will assess these complete exposure pathways for risks to non-target aquatic and terrestrial organisms.

In addition to the consumption of contaminated yellow jacket nest contents, the presence of meat-based bait raises the concern on the mainland of the United States that omnivorous, scavenging, and predatory mammalian wildlife (such native wildlife is lacking in Hawaii and was not identified as an issue there) could seek out the bait stations, attracted by the smell of the bait. A sufficiently large mammal (e.g. opossum, raccoon, or fox) could easily gain access to the bait box contents as the boxes are not certified pet proof. It is not likely that birds would be attracted to the meat bait in a similar manner as mammals and the baits are very small so no large scent source to attract large bird scavengers and in a bait enclosure so no visual queue for other avian scavengers.

Risks to Aquatic Organisms

For aquatic risk assessment a conservative exposure assumption is that the entire amount of fipronil material is collected by yellow jackets on an acre of land and from the entirety of packages of bait material used to treat an acre of land is left available for runoff from an eroded dead Yellow jacket nest. Owing to the slow kill nature of fipronil, it is likely that a Yellowjacket nest will accumulate pesticide in excess of the amount needed to destroy a nest. This simple point source of collected material would be very conservative and maximally result in the following loadings:

Yellow-Jacket Nest Killer: 119 mg fipronil/acre or 0.00026 lb/acre (0.00029 kg/ha)

Assuming the toxicity profile and fate profile for fipronil and degradates has remained unchanged since the 2007 RED, the risk assessment findings from the RED would be useful as a comparison of the yellow jacket application to the risks estimated for application of fipronil in other residential/turf scenarios at similar loadings. The 2007 RED reports that no aquatic risk concerns for the broadcast fire ant residential use HG 61743AE (i.e., no RQs equal to or exceeding Agency levels of concern) at a rate of 0.002 kg/ha (0.0022 lb/acre or 7 to 54 times greater than the assumed rates for the proposed new use).

Because the effective maximal and highly conservative application rates of the two yellow jacket products are below that modelled for broadcast fire ant residential use of HG 61743AE, it is reasonable to predict no aquatic organism concerns for these products.

Risks Terrestrial Organisms

Mammals

Because the bait stations contain meat product, it is possible that a sufficiently large mammal (e.g. opossum, raccoon, and fox) may be attracted to the stations, and if not elevated sufficiently off the ground, the stations may be accessed by these organisms. In addition, a sufficiently large mammal may also consume the bait fipronil in an excavated dead Yellow jacket nest. EFED has limited the assessment to parent fipronil as the material in the bait packages is shielded from the elements, and the contents of killed Yellowjacket nests would be highly labile and likely only attractive for a brief period; thereby limiting the extent to which the fipronil in either the station or nest would convert to degradates. In either case the conservative maximum amount of bait available over an acre at any given time would be:

[REDACTED]

Yellow Jacket Nest Killer: 119 mg fipronil/acre

Conservatively assuming that amount is consumed by a 1000 g mammal, a reasonable sized organism (e.g. opossum, raccoon, or fox) that might break open bait stations or excavated a dead insect nest, the exposure maximally could be:

[REDACTED]

Yellow Jacket Nest Killer: 119 mg fipronil/1000 g-bw or 119 mg/kg-bw

The 2007 RED reports an acute lethal endpoint of 74.61 mg/kg-bw for fipronil for a 1000 g mammal. Comparing this endpoint to the maximal exposures would result in the following acute risk quotients:

[REDACTED]

Yellow-Jacket Nest Killer: $119 \text{ mg/kg-bw} / 74.69 \text{ mg/kg-bw} = 1.6$

The acute RQ values above both exceed the acute level of concern (LOC 0.1) for Federally listed mammals. Only the Yellow Jacket Nest Killer acute RQ exceeds the non-listed mammal LOC (0.5). [REDACTED]

[REDACTED] For the Yellow Jacket Nest Killer, the consumption of three bait boxes or a third of the package contents would still trigger acute non-listed mammal concerns and consumption of even one station would exceed the potential for concerns for listed mammals.

The 2007 RED reports a chronic reproduction effects threshold of 2.03 mg/kg-bw for a 1000g mammal. Comparing this endpoint to the maximal exposures would result in the following chronic risk quotients:

[REDACTED]

$$\text{Yellow Jacket Nest Killer: } 119 \text{ mg/kg-bw} / 2.03 \text{ mg/kg-bw} = 58.6$$

Both products' chronic RQs exceed the listed and non-listed mammal chronic LOC (1.0). Even taking an assumption of lesser accessing efficiency of bait stations, for example only one station (<10% of the total rate per acre as yellow Jacket Nest Killer is applied at a rate of 4 stations per 10,000 ft²) would still exceed the chronic level of concern for Yellow Jacket Nest killer product..

Birds

It is not expected that birds will consume the bait directly owing to the use in a confined bait station. Birds might feed incidentally on yellow jackets transporting the bait back to the subterranean nest. Taking a conservative assumption that such feeding would result in exposures similar to broadcast outdoor application of fipronil it is possible to approximate risk by comparison to those modelled in the 2007 RED risk assessment. The RED concluded that a use of Over'N Out broadcast at 0.01 kg/ha (0.009 lb/acre), assuming 100 percent availability of material, did not trigger avian risk concerns. **Because the effective maximal and highly conservative application rates of the two yellow jacket products are 1-2 orders of magnitude below that modelled for broadcast of Over'N Out, it is reasonable to predict no avian concerns for these products.**

Plants

EFED does not consider terrestrial plants to be at risk of direct exposure to the yellow jacket bait materials. They are confined to bait stations until the target insects transport the material to a subterranean nest. **The opportunity for plant exposure is assumed negligible, and therefore risk to plants is not of concern.**

Terrestrial Invertebrates

While EFED does not consider exposure or risks of concern likely for honeybees, the attractiveness of the material for other insects (e.g. carrion flies and carrion beetles) cannot be ruled out and so risks to these organisms cannot be precluded.

Drinking Water Assessment

The proposed application rates ([REDACTED] Yellow Jacket Nest Killer: 0.00029 kg/ha) are orders of magnitude lower than the application rates (range = 0.0032 to 0.1456 kg/ha or 0.00358 to 0.1632 lb/acre) evaluated in the previous drinking water assessment (DWA) conducted at the time of the RED (USEPA 2006; D322415+). **Because the application rates are 1-3 orders of magnitude lower than currently registered uses, it is the Agency's opinion that a DWA for these proposed uses is not needed at this time.**

Overall Risk Conclusions

EFED concludes the following regarding non-target organism risks and drinking water:

All Aquatic organisms:	No risks of concern
Terrestria plants:	No risks of concern
Birds:	No risks of concern
Terrestrial Invertebrates:	Honeybees not of concern because the baits are un-attractive. It is presumed that other terrestrial invertebrates responding to a meat-based bait (eg. carrion flies and beetles) may be attracted and intoxicated by the products.
Mammals:	Acute and chronic risk concerns through consumption of either bait taken from non-pet certified bait stations or from material scavenged from killed target organism nests. The lethal risk concerns are less likely as multiple bait stations must be scavenged to reach a concern level. However, the reproduction effect associated chronic concerns are potentially more confident, especially for the Yellow-Jacket Net Killer may be enough to trigger a concern.
Drinking Water:	Available Drinking water estimates provided by previous evaluations are conservatively representative of this use and no new estimate specific for this use is needed at this time.

References

- USEPA. 2006. Revision of in Response to Registrant Comments on Comparative Drinking Water Assessment for Proposed and Registered Fipronil Uses. Office of Pesticides Programs. June 26, 2006. (DP 322415, 319940, and 328892)
- USEPA. 2007. Ecological Risk Assessment for Fipronil Uses. Office of Pesticides Programs. February 6, 2007. (DP 331595, 331519, 331593, 329522, 314530, 332424, 325983, 326009, 326000, 325999, 325997, 325990, 326003, 331867, 314530, 322414, 314197, 331714, 331713, 313295, 331872, and 335805)

Ciarlo, Timothy

From: David Dawe <dhdawe@dhdawe.com>
Sent: Wednesday, June 28, 2017 10:28 AM *Resubmission #10*
To: Ciarlo, Timothy
Cc: Davis, Kable; IVB1; 'Rick Matthews'
Subject: RE: 90354-E Efficacy
Attachments: YellowJacketKiller-PackageText- Revision 6-28-17.pdf

Tim,

Thanks for being patient - here is the corrected copy.

Dave

From: Ciarlo, Timothy [mailto:Ciarlo.Timothy@epa.gov]
Sent: Wednesday, June 28, 2017 10:22 AM
To: David Dawe <dhdawe@dhdawe.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews' [REDACTED]
Subject: RE: 90354-E Efficacy

Thanks, Dave.

We still need to change "booklet" on page 1 to "insert." The states interpret a booklet to mean a fold-out label affixed to the outside of a container. Insert signifies additional labelling within the carton/box, which I think is the case here.

Please make this change and respond back with a revised label.

Thanks,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov
Phone: 703-347-8082

From: David Dawe [mailto:dhdawe@dhdawe.com]
Sent: Tuesday, June 27, 2017 4:12 PM *Resubmission #9*
To: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews' [REDACTED]
Subject: RE: 90354-E Efficacy

Tim,

Revisions requested. I added the dropper bottle label to the last page of the label.

Dave

Personal privacy information

Personal privacy information

From: Ciarlo, Timothy [mailto:Ciarlo.Timothy@epa.gov]
Sent: Tuesday, June 27, 2017 10:12 AM
To: David Dawe <dhdawe@dhdawe.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews' [REDACTED]
Subject: RE: 90354-E Efficacy

Hi Dave,

We're getting closer. I'm attaching a PDF with additional label comments. The dropper bottle will need to be labeled since it will contain the diluted product. Aside from that, all comments are very minor.

Also, the CSF and Formulator's Exemption form need to be corrected – the company number of the re-pack product is wrong. They need to refer to [REDACTED] No need to change the dates on either of these documents.

Please let me know if you have any questions.

Regards,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov
Phone: 703-347-8082

From: David Dawe [mailto:dhdawe@dhdawe.com]
Sent: Monday, June 26, 2017 3:55 PM *Resubmission # 8*
To: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews' [REDACTED]
Subject: RE: 90354-E Efficacy

Tim,

Here are the revisions requested. By the way, we did not see these in another version, but they needed to be fixed. I hope these take care of everything.

Thanks.

Dave

From: Ciarlo, Timothy [mailto:Ciarlo.Timothy@epa.gov]
Sent: Monday, June 26, 2017 10:14 AM
To: David Dawe <dhdawe@dhdawe.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews' [REDACTED]
Subject: RE: 90354-E Efficacy

Hi Dave,

Happy Monday. Alright, the data matrix and Formulator's Exemption Statement look to be in order. There are 4 items on the proposed label that still need to be addressed. Please see the attached PDF and respond back with a revised label. These comments were included in our previous round. If anything is unclear, please let me know.

Thanks,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov
Phone: 703-347-8082

From: David Dawe [<mailto:dhdawe@dhdawe.com>]
Sent: Friday, June 23, 2017 4:20 PM *Resubmission #7*
To: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews' [REDACTED]
Subject: RE: 90354-E Efficacy

Sorry Tim, it must be Friday afternoon.

Dave

From: Ciarlo, Timothy [<mailto:Ciarlo.Timothy@epa.gov>]
Sent: Friday, June 23, 2017 4:10 PM
To: David Dawe <dhdawe@dhdawe.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews' [REDACTED]
Subject: RE: 90354-E Efficacy

Thanks, Dave. I'll review this label and get back in touch with you Monday.

I just noticed that the product name on the data matrix should read "Yellow Jacket Killer!" Could you make this additional change for me? I know this is a tedious process, and I appreciate your patience.

Regards,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov
Phone: 703-347-8082

From: David Dawe [<mailto:dhdawe@dhdawe.com>]
Sent: Friday, June 23, 2017 3:50 PM *Resubmission #6*
To: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>

Personal privacy information

Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews'
Subject: RE: 90354-E Efficacy

Tim,

I think we got everything this time. Sorry about the data matrix – I grabbed the wrong file. Let me know if you need anything else. Thanks.

Dave

From: Ciarlo, Timothy [<mailto:Ciarlo.Timothy@epa.gov>]
Sent: Friday, June 23, 2017 11:53 AM
To: David Dawe <dhdawe@dhdawe.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews'
Subject: RE: 90354-E Efficacy

Dave,

The only thing that will need to be changed on the Formulator's Exemption Statement is the "date of CSF" box towards the top. Currently, it says 11/14/15. It should be changed to 4/17/17.

Thanks,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov
Phone: 703-347-8082

From: David Dawe [<mailto:dhdawe@dhdawe.com>]
Sent: Friday, June 23, 2017 11:33 AM
To: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews'
Subject: RE: 90354-E Efficacy

Tim,

Will review and make necessary changes. The data matrix was done and will be revised. WE submitted the formulators exemption statement originally so I will include a copy – will that satisfy the requirement?

Dave

From: Ciarlo, Timothy [<mailto:Ciarlo.Timothy@epa.gov>]
Sent: Friday, June 23, 2017 10:59 AM
To: David Dawe <dhdawe@dhdawe.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews'
Subject: RE: 90354-E Efficacy

Personal privacy information

Hi Dave,

Thanks for the revised label. Bo and I had several additional comments, which hopefully should be the last of them. Please see the attached PDF version of the label.

Also attached is a pre-decisional letter since today is the pre-decisional due date. The PRIA date is still 7/7/17. If you would, please confirm receipt of this letter by replying to this email.

The data matrix dated 6/20/17 will need to be revised. Recall from a conversation back in April that you were going to use the Formulator's Exemption to satisfy generic data requirements, and that you were going to list only the supporting efficacy data on the data matrix. The version dated 4/17/17 (attached to this email) was nearly correct – you just needed to add MRID 49797201 to it.

Lastly, the Formulator's Exemption Statement dated 12/16/15 (also attached) should be revised so that the date of CSF referenced on it corresponds with that of the accepted Basic CSF, which is 4/17/17.

I will stand by for the following:

1. Revised label
2. Revised data matrix
3. Revised Formulator's Exemption Statement

We're close. Please let me know if you have any questions or concerns.

Regards,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov
Phone: 703-347-8082

From: David Dawe [<mailto:dhdawe@dhdawe.com>]
Sent: Thursday, June 22, 2017 3:35 PM *Resubmission #5*
To: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews'
Subject: RE: 90354-E Efficacy

Tim,

Attached are the revised label and the revised data matrix. Let me know if there are any problems or concerns.

Thanks.

Dave

From: Ciarlo, Timothy [<mailto:Ciarlo.Timothy@epa.gov>]
Sent: Tuesday, June 20, 2017 11:39 AM
To: David Dawe <dhdawe@dhdawe.com>

Personal privacy information

Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews'
Subject: RE: 90354-E Efficacy

Hi Dave,

I've made some comments on the label documents you emailed to me last week. Please note that you will need to combine these documents into a single PDF. The master label which will be stamped needs to contain all labeling.

In addition, please add MRID 49797201 to the data matrix. This was upgraded from "unacceptable" to "supplemental" based on your efficacy rebuttal. You can email this directly to me.

Please let me know if you have any questions or if any of my comments are unclear. This label review is a priority item for us this week since it needs to be finalized by 6/23.

Regards,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov
Phone: 703-347-8082

From: David Dawe [<mailto:dhdawe@dhdawe.com>]
Sent: Friday, June 16, 2017 3:34 PM *Resubmission #4*
To: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews'
Subject: RE: 90354-E Efficacy

Tim,

Attached, please find the revised label for your review.

Thanks.

Dave

From: Ciarlo, Timothy [<mailto:Ciarlo.Timothy@epa.gov>]
Sent: Friday, June 16, 2017 2:42 PM
To: David Dawe <dhdawe@dhdawe.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews'
Subject: RE: 90354-E Efficacy

Hi Dave,

Yes, please go ahead and submit the revised label via email. I will then review it based on the 5/23 efficacy DER and will let you know if any further edits are required. If and when we get it to where it needs to be, we should be able to register the product. We'll need to complete all label edits by 6/23, which should be doable.

Regards,

Personal privacy information

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov
Phone: 703-347-8082

From: David Dawe [<mailto:dhdawe@dhdawe.com>]
Sent: Friday, June 16, 2017 2:35 PM
To: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews' [REDACTED]
Subject: RE: 90354-E Efficacy

Tim,

I tried your phone number you gave in the email but it goes to a general answer system and will not connect to your voice mail. If we submit the revised label I that all that is required? if it is reviewed and is acceptable then will our registration be approved?

We have revised the label and will submit it but wanted to know where that puts us in the process. Thanks.

Dave

From: Ciarlo, Timothy [<mailto:Ciarlo.Timothy@epa.gov>]
Sent: Thursday, June 15, 2017 4:32 PM
To: David Dawe <dhdawe@dhdawe.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews' [REDACTED]
Subject: RE: 90354-E Efficacy

Hi Dave,

At this point, you can either proceed with the label revisions based on the efficacy rebuttal DER dated 5/23/2017 or withdraw the action. As I mentioned previously, the Agency's official review of an efficacy rebuttal marks the end of the efficacy review process. RD management will not support another extension of the PRIA due date for the same reason as the first extension. If you were to withdraw, you could submit an application package in the future which can provide adequate efficacy data to support the label claims you're seeking. The efficacy data associated with this application package can only support the limited claims detailed in the 5/23/2017 DER.

As far as the PRIA timeline goes, the PRIA due date is 7/7/2017, and the pre-decisional due date is 6/23/2017. We need to have everything figured out and the label reviewed by 6/23/2017.

Regards,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov
Phone: 703-347-8082

Personal privacy information

From: David Dawe [<mailto:dhdawe@dhdawe.com>]
Sent: Thursday, June 15, 2017 3:50 PM
To: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Rick Matthews' [REDACTED]
Subject: RE: 90354-E Efficacy

Tim,

We got the DER and had a couple of questions.

We need to discuss your definition of controls and how we should incorporate controls in our field tests. We believed that we had the correct "controls" in our test design.

What are our time constraints as to the new label and directions for use.

We have 3 published international studies pertaining to the transfer properties of Fipronil. Two studies were conducted with yellow jacket baiting and the other study was on ant colonies. Will the EPA allow us to note the transfer properties on the new label.

Do we have a new PRIA date?

Dave

From: Ciarlo, Timothy [<mailto:Ciarlo.Timothy@epa.gov>]
Sent: Tuesday, May 30, 2017 1:34 PM
To: David Dawe <dhdawe@dhdawe.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: 90354-E Efficacy

Password: [REDACTED]

From: Ciarlo, Timothy
Sent: Tuesday, May 30, 2017 1:33 PM
To: 'David Dawe' <dhdawe@dhdawe.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: 90354-E Efficacy

Hi Dave,

I received the review of your efficacy rebuttal for 90354-E and wanted to pass it to you for your awareness. I have password-protected it and will send the password in a follow-up email.

Note that after additional review by entomologists in the Pesticide Efficacy Review Committee, some efficacy claims are now acceptable and we now have a path forward. That said, the label will need to be modified in accordance with the attached document. "Nest" claims, or any type of claim that implies the product kills yellow jacket nests are still unacceptable. The attached PDF contains a version of the label with Agency comments which can serve as a starting point for us in the label review process.

The Agency's review of your rebuttal marks the end of the efficacy review process. If you would rather not register this product without nest claims, you are still free to withdraw this action.

Please confirm receipt of this document by replying to this email.

Regards,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov
Phone: 703-347-8082

S: 1002525

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☒ Yes ☐ No

Application Type: Pending Product Amendment

Fee For Service: ☐ Yes ☒ No

Company: 90354 2 STAR SOLUTION INC

Billable: ☐ Yes ☒ No

V

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 3

Product #: 90354-E

Product Name: YELLOW JACKET NEST KILLER!

Overide#:

Me Too

Me Too Product

☐ Section3:

Name:

Application Date: 18-Apr-2017

OPP Rec'd Date: 21-Apr-2017

Front End Date: 21-Apr-2017

Risk Manager Send Date: 24-Apr-2017

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Amendment to a Pending Application

Receipt Content

CSF

View/Edit

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

CSF Resubmission

Resub 3 4/21/17
Data matrix + CSF
dtd 4/17/17.

COPY - CHEM

DATA PACKAGE BEAN SHEET

Date: 08-Apr-2016

Page 1 of 2

Decision #: 512219

DP #: (432824)

PRIA

Parent DP #:

Submission #: 984341

E-Sub #:

*Resubmission
2*

*** Registration Information ***

Registration: 90354-E - YELLOW JACKET NEST KILLER!

Company: 90354 - 2 STAR SOLUTION INC

Risk Manager: RM 03 - Kable Davis - (703) 306-0415 Room# PY1 S-7723

Risk Manager Reviewer: Timothy Ciarlo TCIARLO

Sent Date:

PRIA Due Date: 07-Mar-2017

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R320) NEW PRODUCT;NEW PHYSICAL FORM;REQUIRES DATA REVIEW IN SCIENCE DI

Ingredients: 129121, Fipronil(9.1%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 08-Apr-2016

Due Back:

DP Ingredient: 129121, Fipronil

DP Title: New Physical Form Chem Review

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / CITAB

Last Possible Science Due Date: 06-Jan-2017

Team Name: CHEM

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Attention Chemistry Reviewer: Please complete a technical screen by 5/27/2016.

Please review the cited product chemistry data and determine if they are acceptable for product registration. The proposed product is a new physical form of a fipronil bait designed to kill yellowjackets outdoors. I have included the following:

1. Cover letter dated 12/16/2015
2. Data matrix dated 4/6/2016
3. Proposed label
4. Basic CSF dated 12/16/2015

MRID 44769901 contains the cited chem data to be reviewed and is available in Documentum. Please let me know if you have any questions.

Thanks,
Tim Ciarlo, 703-347-8082

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
44769901		Cookinham, J. (1999) Termidor 0.8SC Product Chemistry: Lab Project Number: 5375-F: 0928-052. Unpublished study prepared by Midwest Research Institute. 99 p. {OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750, 830.1800, 830.6302, 830.6303, 830.6304, 830.7300, 830.7000, 830.6314, 830.6315, 830.7100}	63-0/Reports of Multiple phys/chem Characteristics	Pass (20-Aug-2010)
44769901		Cookinham, J. (1999) Termidor 0.8SC Product Chemistry: Lab Project Number: 5375-F: 0928-052. Unpublished study prepared by Midwest Research Institute. 99 p. {OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750, 830.1800, 830.6302, 830.6303, 830.6304, 830.7300, 830.7000, 830.6314, 830.6315, 830.7100}	830.1550/Product Identity and composition	Pass (20-Aug-2010)
44769901		Cookinham, J. (1999) Termidor 0.8SC Product Chemistry: Lab Project Number: 5375-F: 0928-052. Unpublished study prepared by Midwest Research Institute. 99 p. {OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750, 830.1800, 830.6302, 830.6303, 830.6304, 830.7300, 830.7000, 830.6314, 830.6315, 830.7100}	830.1600/Description of materials used to produce the product	Pass (20-Aug-2010)
44769901		Cookinham, J. (1999) Termidor 0.8SC Product Chemistry: Lab Project Number: 5375-F: 0928-052. Unpublished study prepared by Midwest Research Institute. 99 p. {OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750, 830.1800, 830.6302, 830.6303, 830.6304, 830.7300, 830.7000, 830.6314, 830.6315, 830.7100}	830.1670/Discussion of formation of impurities	Pass (20-Aug-2010)
44769901		Cookinham, J. (1999) Termidor 0.8SC Product Chemistry: Lab Project Number: 5375-F: 0928-052. Unpublished study prepared by Midwest Research Institute. 99 p. {OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750, 830.1800, 830.6302, 830.6303, 830.6304, 830.7300, 830.7000, 830.6314, 830.6315, 830.7100}	830.1700/Preliminary analysis	Pass (20-Aug-2010)
44769901		Cookinham, J. (1999) Termidor 0.8SC Product Chemistry: Lab Project Number: 5375-F: 0928-052. Unpublished study prepared by Midwest Research Institute. 99 p. {OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750, 830.1800, 830.6302, 830.6303, 830.6304, 830.7300, 830.7000, 830.6314, 830.6315, 830.7100}	830.1750/Certified limits	Pass (20-Aug-2010)
44769901		Cookinham, J. (1999) Termidor 0.8SC Product Chemistry: Lab Project Number: 5375-F: 0928-052. Unpublished study prepared by Midwest Research Institute. 99 p. {OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750, 830.1800, 830.6302, 830.6303, 830.6304, 830.7300, 830.7000, 830.6314, 830.6315, 830.7100}	830.1800/Enforcement analytical method	Pass (20-Aug-2010)

Ciarlo, Timothy

From: David Dawe <dhdawe@dhdawe.com>
Sent: Wednesday, March 22, 2017 10:24 AM
To: Ciarlo, Timothy; Davis, Kable
Cc: 'Rick'; Mathur, Shyam
Subject: Chemistry Deficiency Response
Attachments: EPA DER Rebuttal and Comments 2-23-17 Revised.pdf; Jacket Copy redacted releasable 53883-279 Vol. 1 Part 1 -Highlighted.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Tim,

I apologize for the delay, as I was working on redoing the data matrix as we discussed I did a little digging on the available information you have at EPA and found that during the course of registering the [REDACTED] the Agency declared that these two end-use products were substantially similar, that is [REDACTED]

Since I was expecting to resolve this question, I held the submission of the hard copy of the efficacy rebuttal anticipating that we could turn in both at the same time. Wanted to give you an update.

Dave

David H. Dawe, Ph.D.
D.H. Dawe & Associates, LLC.
16841 Four Season Dr.
Dumfries, VA 22025
Phone: (703) 590-7570
Cell: (559) 960-2245
email: dhdawe@dhdawe.com
Web Site: www.dhdawe.com

From: David Dawe [mailto:dhdawe@dhdawe.com]
Sent: Friday, February 24, 2017 11:29 AM
To: 'Ciarlo, Timothy' <Ciarlo.Timothy@epa.gov>
Cc: 'Rick' [REDACTED]
Subject: RE: Rebuttal

Tim,

Personal privacy information

Product ingredient source information may be entitled to confidential treatment

Here is a copy of the rebuttal. We are working on the Data Matrix and it will be done Monday. I will turn in the rebuttal, data matrix and a cover letter on Monday through Front End. Do you need three copies?

Dave

David H. Dawe, Ph.D.

D.H. Dawe & Associates, LLC.

16841 Four Season Dr.

Dumfries, VA 22025

Phone: (703) 590-7570

Cell: (559) 960-2245

email: dhdawe@dhdawe.com

Web Site: www.dhdawe.com

From: Ciarlo, Timothy [<mailto:Ciarlo.Timothy@epa.gov>]

Sent: Friday, February 24, 2017 10:23 AM

To: David Dawe <dhdawe@dhdawe.com>

Subject: RE: Rebuttal

Dave,

If you can submit it through the CDX Portal, that would be ideal. Otherwise, yes, you should submit a hard copy through the Front End. Either way, if you could email me a courtesy copy of the rebuttal/data matrix/cover letter, this will let us get the ball rolling sooner and save us all some time.

Thanks,

Tim Ciarlo

Entomologist

Environmental Protection Agency

OCSP/OPP/RD/IVB1

Email: Ciarlo.Timothy@epa.gov

Phone: 703-347-8082

From: David Dawe [<mailto:dhdawe@dhdawe.com>]

Sent: Friday, February 24, 2017 10:19 AM

To: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>

Subject: RE: Rebuttal

Tim,

Do you need a hard copy submitted through Front End?

Dave

David H. Dawe, Ph.D.

D.H. Dawe & Associates, LLC.

16841 Four Season Dr.

Dumfries, VA 22025

Phone: (703) 590-7570
Cell: (559) 960-2245
email: dhdawe@dhdawe.com
Web Site: www.dhdawe.com

From: Ciarlo, Timothy [<mailto:Ciarlo.Timothy@epa.gov>]
Sent: Friday, February 24, 2017 8:29 AM
To: David Dawe <dhdawe@dhdawe.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; 'Rick' [REDACTED]
Subject: RE: Rebuttal

Hi Dave,

Thanks for the update. I am processing the renegotiation paperwork today for a PRIA date of 7/7/17.

Regards,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov
Phone: 703-347-8082

From: David Dawe [<mailto:dhdawe@dhdawe.com>]
Sent: Thursday, February 23, 2017 4:50 PM
To: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; 'Rick' [REDACTED]
Subject: Rebuttal

Tim and Bo,

We have had some problems with the internet today between me and the company. We will have the rebuttal to you tomorrow I hope.

Dave

David H. Dawe, Ph.D.
D.H. Dawe & Associates, LLC.
16841 Four Season Dr.
Dumfries, VA 22025
Phone: (703) 590-7570
Cell: (559) 960-2245
email: dhdawe@dhdawe.com
Web Site: www.dhdawe.com

Personal privacy information

Ciarlo, Timothy

From: Ciarlo, Timothy
Sent: Thursday, January 19, 2017 10:44 AM
To: 'David Dawe'
Cc: Davis, Kable; Britton, Cathryn; IVB1
Subject: RE: 90354-E 75-Day Letter

Hi Dave,

Please see the product chemistry review, attached. It is password protected. I'll send the password in a follow-up email.

As we move along in the review process, some additional questions have arisen mainly revolving around the proposed label. We'll need some clarity on these issues before we can move forward, and I am hopeful you can better our understanding of your proposed product.

The Directions for Use instruct the applicator to mix up a dilute fipronil solution by first filling a dropper bottle with clean water to a fill line marked on the bottle. Then, the applicator is instructed to add the 0.3 ml of 9.1% fipronil to the dropper bottle and shake well. Once this step is complete, the applicator can add 2 drops of the dilute solution to each cube of bait. So the question then is: What volume of water is added to the dropper bottle? And then, how much fipronil is contained in each drop? It may be possible to extrapolate the answer to the latter question if we know how many drops the filled dropper bottle delivers. We need to know the application rate in terms of unit of mass of fipronil per unit of area. Right now we have no way of knowing this.

Also, it seems likely that a user of this product will have leftover dilute fipronil remaining in the dropper bottle. What should the user do with it? How will the dropper bottle be labeled?

I also had a few questions regarding the efficacy study submitted to support this product (MRID 49797201). This study looked at field efficacy across 7 nests from 5 separate sites. It mentions that 3 of the 7 nests were excavated once nest activity ceased. Are you able to tell us which ones? Also, what was the size of each site, and does it correspond to the Directions for Use on the proposed label? The label right now says to use 4 stations per 10,000 ft², with 6-8 drops of dilute solution per station per day for up to 5 consecutive days. This is why it is critical to know the application rate. Where was each bait station placed in relation to each nest? A map of each site would be helpful if you have it. Why were additional bait stations placed out at 4 of the 5 sites after the study was initiated? Could you explain why in the vast majority of cases, the bait (both treated and untreated) was reported as uneaten? Were the bait station placements not close enough to the target nests?

Your answers will be greatly helpful in addressing risk issues and efficacy concerns. Please let me know if you have any questions.

Regards,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov
Phone: 703-347-8082

From: David Dawe [mailto:dhdawe@dhdawe.com]
Sent: Thursday, January 19, 2017 10:15 AM
To: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: 90354-E 75-Day Letter

Tim,

Sorry I thought I asked that – please send the chemistry review referenced in the letter via email. The letter addresses dates for our response and I cannot consider our options without knowing what issues have been raised.

Dave

David H. Dawe, Ph.D.
D.H. Dawe & Associates, LLC.
16841 Four Season Dr.
Dumfries, VA 22025
Phone: (703) 590-7570
Cell: (559) 960-2245
email: dhdawe@dhdawe.com
Web Site: www.dhdawe.com

From: Ciarlo, Timothy [mailto:Ciarlo.Timothy@epa.gov]
Sent: Thursday, January 19, 2017 9:54 AM
To: David Dawe <dhdawe@dhdawe.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: 90354-E 75-Day Letter

Hi Dave,

Due to CBI procedures, I can't send you the chemistry review referenced in the letter unless you ask that it be sent via email. Alternatively, it can be sent via certified mail. Please let me know how you'd like me to send it to you.

Regards,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov
Phone: 703-347-8082

From: David Dawe [mailto:dhdawe@dhdawe.com]
Sent: Thursday, January 19, 2017 9:48 AM
To: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: 90354-E 75-Day Letter

Yes, please send the details of the review.

Dave

David H. Dawe, Ph.D.

D.H.Dawe & Associates, LLC.

16841 Four Season Dr.

Dumfries, VA 22025

Phone: (703) 590-7570

Cell: (559) 960-2245

email: dhdawe@dhdawe.com

Web Site: www.dhdawe.com

From: Ciarlo, Timothy [<mailto:Ciarlo.Timothy@epa.gov>]

Sent: Thursday, January 19, 2017 9:41 AM

To: David Dawe <dhdawe@dhdawe.com>

Cc: Davis, Kable <Davis.Kable@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; IVB1 <IVB1@epa.gov>

Subject: RE: 90354-E 75-Day Letter

Dave,

Please see the 75-day letter, attached. If you'd like to see the chemistry review referenced therein, please let me know how you'd like me to send it to you.

Regards,

Tim Ciarlo

Entomologist

Environmental Protection Agency

OCSPP/OPP/RD/IVB1

Email: Ciarlo.Timothy@epa.gov

Phone: 703-347-8082

From: David Dawe [<mailto:dhdawe@dhdawe.com>]

Sent: Thursday, January 19, 2017 9:28 AM

To: Ciarlo, Timothy <Ciarlo.Timothy@epa.gov>

Cc: Davis, Kable <Davis.Kable@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; IVB1 <IVB1@epa.gov>

Subject: RE: 90354-E 75-Day Letter

Please send the letter via email. Thanks.

Dave

David H. Dawe, Ph.D.

D.H.Dawe & Associates, LLC.

16841 Four Season Dr.

Dumfries, VA 22025

Phone: (703) 590-7570

Cell: (559) 960-2245

email: dhdawe@dhdawe.com

Web Site: www.dhdawe.com

From: Ciarlo, Timothy [<mailto:Ciarlo.Timothy@epa.gov>]
Sent: Thursday, January 19, 2017 8:49 AM
To: David Dawe <dhdawe@dhdawe.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: 90354-E 75-Day Letter

Hi Dave,

Would you kindly confirm receipt of the 75-day letter dated 1/18/17 by replying to this email? If you have any questions, please don't hesitate to ask.

Regards,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov
Phone: 703-347-8082

From: Ciarlo, Timothy
Sent: Wednesday, January 18, 2017 1:45 PM
To: 'David Dawe' <dhdawe@dhdawe.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: 90354-E 75-Day Letter

Hi Dave,

This email is in regards to your R320 application for registration of 90354-E. Attached, please see a 75-Day deficiency letter which identifies a product chemistry deficiency that will need to be addressed before we can move forward. Due to CBI procedures, I can't send you the chemistry review referenced in the letter unless you ask that it be sent via email. Alternatively, it can be sent via certified mail. How would you like me to send it to you?

Regards,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov
Phone: 703-347-8082

Mathur, Shyam

From: David Dawe <dhdawe@dhdawe.com>
Sent: Monday, January 09, 2017 3:01 PM
To: Mathur, Shyam
Subject: 90354-E
Attachments: CSF Yellow Jacket Nest Killer Revised 1-9-17.pdf

Shyam,

Attached is the revised CSF for Yellow Jacket Nest Killer as we agreed. If there are questions, please let me know.

Dave

David H. Dawe, Ph.D.

D.H. Dawe & Associates, LLC.

16841 Four Season Dr.

Dumfries, VA 22025

Phone: (703) 590-7570

Cell: (559) 960-2245

email: dhdawe@dhdawe.com

Web Site: www.dhdawe.com

Confidential Statement of Formula May be entitled to confidential treatment